Facemasks in the protection of hospitals healthcare workers (HCW) in resource poor settings

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FACEMASKS IN THE PROTECTION OF

HOSPITALS HEALTHCARE WORKERS (HCW)

IN RESOURCE POOR SETTINGS

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This thesis is in fulfilment of the requirements for the degree of

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Currently there is an ongoing debate and a dearth of evidence around the efficacy of facemasks and respirators. Most studies have been observational and there is a lack of trial data around use and re-use of facemasks in the healthcare setting. Due to the lack of high quality studies, I hypothesised that there would be huge variations in the policies and practices around the use of facemasks and respirators in the healthcare setting. This thesis therefore aims to examine the policies and practices around the use of these products in low resource countries.

Five studies were conducted at varying administrative levels. In the first study, publicly available policies and guidelines around the use of facemasks/respirators were examined to describe areas of consistency, as well as gaps in the recommendations. In the second study, infection control stakeholders were interviewed from China, Pakistan and Vietnam to further explore the issues, which arose during the guideline review. Next, hospitals from the three countries were surveyed to examine practices around the use of facemasks/ respirators and to examine the translation of policies into practice. Samples of facemasks and respirators were also collected and tested. In the fourth study, focus groups were undertaken to examine the knowledge, attitudes and practices of Vietnamese hospital HCWs towards the use of masks/respirators. The fifth study examined the factors associated with compliance of Vietnamese HCWs with the use of various types of facemasks. In addition, the available evidence around the efficacy and use of cloth masks was reviewed. These studies provide new data around factors impacting on the use of facemasks and respirators in resource poor settings. Inconsistencies and gaps were identified in the reviewed polices, which highlight that there is a need to develop a comprehensive and uniform policy around the use of facemasks/respirators. Practices around the use of facemasks and respirators are influenced by organizational and personal factors and understanding these factors will assist with the development of strategies to improve staff compliance with respiratory protection. On the basis of these studies, recommendations have been developed around the use of facemasks and respirators in low resource settings.

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'I hereby declare that this submission is my own work and to the best of my knowledge it contains no materials previously published or written by another person, or substantial proportions of material which have been accepted for the award of any other degree or diploma at UNSW or any other educational institution, except where due acknowledgement is made in the thesis. Any contribution made to the research by others, with whom I have worked at UNSW or elsewhere, is explicitly acknowledged in the thesis. I also declare that the intellectual content of this thesis is the product of my own work, except to the extent that assistance from others in the project's design and conception or in style, presentation and linguistic expression is acknowledged.'

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SUPERVISOR STATEMENT

I hereby certify that all co-authors of the published or submitted papers agree to Abrar Ahmad Chughtai submitting those papers as part of his/her Doctoral Thesis.

Signed .....

Date 23/3/15

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I dedicate this thesis to my parents for all the sacrifices they had made for me. They helped me with every step of my life and encouraged me to start the PhD program.

ABSTRACT

Currently there is an ongoing debate and a dearth of evidence around the efficacy of facemasks and respirators. Most studies have been observational and there is a lack of trial data around use and re-use of facemasks in the healthcare setting. Due to the lack of high quality studies, I hypothesised that there would be huge variations in the policies and practices around the use of facemasks and respirators in the healthcare setting. This thesis therefore aims to examine the policies and practices around the use of these products in low resource countries.

Five studies were conducted at varying administrative levels. In the first study, publicly available policies and guidelines around the use of facemasks/respirators were examined to describe areas of consistency, as well as gaps in the recommendations. In the second study, infection control stakeholders were interviewed from China, Pakistan and Vietnam to further explore the issues, which arose during the guideline review. Next, hospitals from the three countries were surveyed to examine practices around the use of facemasks/ respirators and to examine the translation of policies into practice. Samples of facemasks and respirators were also collected and tested. In the fourth study, focus groups were undertaken to examine the knowledge, attitudes and practices of Vietnamese hospital HCWs towards the use of masks/respirators. The fifth study examined the factors associated with compliance of Vietnamese HCWs with the use of various types of facemasks. In addition, the available evidence around the efficacy and use of cloth masks was reviewed.

These studies provide new data around factors impacting on the use of facemasks and respirators in resource poor settings. Inconsistencies and gaps were identified in the reviewed polices, which highlight that there is a need to develop a comprehensive and uniform policy around the use of facemasks/respirators. Practices around the use of facemasks and respirators are influenced by organizational and personal factors and understanding these factors will assist with the development of strategies to improve staff

compliance with respiratory protection. On the basis of these studies, recommendations have been developed around the use of facemasks and respirators in low resource settings.

LIST OF ABBREVIATIONS

AIIR	Airborne infection isolation rooms
AGPs	Aerosol generating procedures
CDC	Centers for Disease Control and Prevention (US)
CFR	Case-fatality ratio
CRI	Clinical respiratory infection
EN	European norm
EVD	Ebola Virus disease
FDA	Food and Drug Administration
FFP (Respirator)	Filtering face piece (Respirator)
H	Hemagglutinin
HCWs	Healthcare workers
HPAI	highly pathogenic avian influenza
ILI	Influenza like illness
IOM	Institute of Medicine (National Academy of Sciences US)
LPAI	Low pathogenic avian influenza
MDR TB	Multi drug resistant TB
MERS-CoV	Middle East respiratory syndrome coronavirus
MSG	Microwave-generated steam
N	Neuraminidase
NIHE	National Institute for Hygiene and Epidemiology
NIOSH	National Institute for Occupational Safety and Health (US)

List of abbreviations

OHSA	Occupational Health and Safety Administration (US)
OT	Operating theatre
PMRC	Pakistan Medical and Research Council
PAPR	Powered air-purifying respirators
PFE	Particle filtration efficacy
PPE	Personal protective equipment
RCT	Randomised control trial
RSV	Respiratory syncytial virus
SARS	Severe acute respiratory syndrome
SWPF	Simulated workplace protection factor
TB	Tuberculosis
TST	Tuberculin skin test
WHO	World Health Organization
XDR TB	Extensively drug resistant TB
UVGI	Ultraviolet germicidal irradiation

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ETHICS APPROVALS

Health department survey (Chapter 3)

Approval for the health department survey was obtained from the Human Research Ethics Advisory (HREA) Panel of the University of New South Wales, Sydney Australia (Approval no 2012-7-40). Approval was also received from the Beijing Center for Disease Control and Prevention (CDC) China, the Pakistan Medical and Research Council (PMRC), Pakistan (Approval no NBC-105) and from the National Institute for Hygiene and Epidemiology (NIHE), Vietnam (Approval no 10-IRB).

Hospital survey (Chapter 4)

Approval for the hospital survey was obtained from the Human Research Ethics Advisory (HREA) Panel of the University of New South Wales, Sydney Australia (Approval 2013-7-02). Approval was also received from the Beijing Center for Disease Control and Prevention (CDC) China, the Pakistan Medical and Research Council (PMRC), Pakistan (Approval no NBC-120) and from the National Institute for Hygiene and Epidemiology (NIHE), Vietnam (Approval no 12-IRB).

Staff level studies (Chapters 5&6)

Ethics approval for these studies was obtained from the Institutional Review Board at the National Institute for Hygiene and Epidemiology (NIHE) (Approval number 05-IRB) and the Human Research Ethics Committee of the University of New South Wales (UNSW), Australia, (HREC approval number 10306).

PUBLICATIONS ARISING FROM THIS THESIS

Peer-reviewed publications

1. **Chughtai AA**, Seale H, MacIntyre CR. Availability, consistency and evidence-base of policies and guidelines on the use of mask and respirator to protect hospital health care workers: a global analysis. BMC research notes. 2013;6:216.

2. **Chughtai AA**, MacIntyre CM, Zheng Y, Wang Q, Toor ZI, Dung TC, Hien NT, Seale H. Examining the policies and guidelines around the use of masks and respirators by healthcare workers in China, Pakistan and Vietnam. Journal of Infection Prevention. 2014: 1-7. DOI: 10.1177/1757177414560251.

3. **Chughtai AA**, Seale H, Chi Dung T, Maher L, Nga PT, MacIntyre CR. Current practices and barriers to the use of facemasks and respirators among hospital-based health care workers in Vietnam. American journal of infection control. 2015;43(1):72-7.

4. **Chughtai AA**, Seale H, MacIntyre CR. Use of cloth masks in the practice of infection control – evidence and policy gaps. International Journal of Infection Control. 2013;9(3):1-12

5. **Chughtai AA**, MacIntyre CR, Ashraf MO, Zheng Y, Yang P, Wang Q, , Dung TC, Hien NT, Seale H. Practices around the use of facemasks and respirators amongst hospital healthcare workers (HCWs) in three diverse populations. 2015. American journal of infection control (In press).

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6. **Chughtai AA**, Seale H, Dung TC, Hayen A, Rahman B, MacIntyre CR. Factors affecting compliance of healthcare workers with the use of facemasks. 2015.

PUBLICATIONS ASSOCIATED WITH THIS THESIS

1. MacIntyre CR, Seale H, Dung TC, Hien NT, Nga PT, **Chughtai AA**, Rahman B, Dwyer DE, Wang Q. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open 2015:e006577.

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3. MacIntyre CR, **Chughtai AA**, Seale H, Richards GA & Davidson PM (2014): Respiratory protection for healthcare workers treating Ebola virus disease (EVD): Are facemasks sufficient to meet occupational health and safety obligations? Int J Nurs Stud 51, 1421-1426.

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7. Bui C, Bethmont A, **Chughtai AA**, Gardner L, Sarkar S, Hassan S, et al. A Systematic Review of the Comparative Epidemiology of Avian and Human Influenza A H5N1 and H7N9 - Lessons and Unanswered Questions. Transboundary and emerging diseases. 2015:1-19. doi:10.1111/tbed.12327

CONFERENCE PROCEEDINGS

1. **Chughtai AA**, MacIntyre CR, Ashraf MO, Toor ZI, Zheng Y, Yang P, Wang Q, , Dung TC, Hien NT, Seale H. Policies and practices around the use of facemasks and respirators. *10th Australian Influenza Symposium Melbourne Australia, 12-13 November 2014 (Oral presentation)*

2. **Chughtai AA**, MacIntyre CR, Ashraf MO, Toor ZI, Zheng Y, Yang P, Wang Q, , Dung TC, Hien NT, Seale H. Policies and practices around the use of facemasks and respirators. *Public health aspects of infectious diseases, Research Symposium, UNSW, Australia, 4 September 2014 (Oral presentation)*

1. **Chughtai AA**, MacIntyre CR, Zheng Y, Wang Q, Toor ZI, Dung TC, Hien NT, Seale H. Examining the policies and guidelines around the use of masks and respirators by healthcare workers in China, Pakistan and Vietnam. *International Congress on Infectious Diseases. South Africa 3-5 April 2014 (Poster)*

2. **Chughtai AA**, MacIntyre CR, Ashraf MO, Zheng Y, Yang P, Wang Q, , Dung TC, Hien NT, Seale H. Examining current practices around the use of masks and respirators amongst healthcare workers in three diverse populations. *International Congress on Infectious Diseases. South Africa 3-5 April 2014 (Poster)*

3. **Chughtai AA**, Seale H, MacIntyre CR. Availability, consistency and evidence-base of policies and guidelines on the use of mask and respirator to protect hospital health care workers: a global analysis. *Options for the Control of Influenza. Cape Town South Africa. September 2013 (Poster)*

4. **Chughtai AA**, Seale H, MacIntyre CR. Use of cloth masks in the practice of infection control – evidence and policy gaps. *Options for the Control of Influenza. Cape Town South Africa. September 2013 (Poster)*

5. **Chughtai AA**, Seale H, MacIntyre CR. Availability, consistency and evidence-base of policies and guidelines on the use of mask and respirator to protect hospital health care workers: a global analysis. *CDC Conference. Canberra. March 2013 (Poster)*

6. **Chughtai AA**, Seale H, MacIntyre CR. Availability, consistency and evidence-base of policies and guidelines on the use of mask and respirator to protect hospital health care workers: a global analysis. *Global Health Conference. UNSW. August, 2012 (Poster)*

7. **Chughtai AA**, Seale H, MacIntyre CR. Availability, consistency and evidence-base of policies and guidelines on the use of mask and respirator to protect hospital health care workers: a global analysis. *Research Symposium. UNSW. September 2012 (Poster)*

AWARDS AND TRAVEL SCHOLARSHIPS

1. Awarded a “Dean’s list” citation in 2013. It is the highest award by the Faculty of Medicine to a research student who has made a significant contribution in their field of study.
2. Travel fellowship from Bill and Malinda Gates Foundation to attend “Options for Control of Influenza” conference in Cape Town South Africa in 2013.
3. The Postgraduate Research Student Support (PRSS) award to attend “International Congress on Infectious Diseases” Conference in Cape Town South Africa 2014

A GUIDE TO THESIS

Through their work activities, hospital healthcare workers (HCWs) are exposed to a wide variety of hazards, including biological, chemical, physical and psychological stressors, but the most important threat is the potential for exposure to infections. Infectious patients present in the hospital, transmit their infections not only to other hospitalized patients, but also to HCWs. Therefore, HCWs are at high risk not only for the acquisition of infections but also for transmitting respiratory, bloodborne and other infections (1-12). Laboratory-acquired infections are also common amongst HCWs (13-15). In addition, HCW conditions and resources are different in developed and developing countries. Much attention has been given to research in developed countries, but less in developing countries, where practices, policies, and levels of protection of routinely used products are unclear.

Facemasks (including medical masks and cloth masks) and N95 respirators are the most common products referred to in guidelines aimed at protecting HCWs from pathogens spread through respiratory aerosols (16-20). However, there is an ongoing debate about the effectiveness of the different products (facemasks and respirators) in healthcare settings. Up until recently, most facemask studies in healthcare settings were observational (case control, cross sectional or case studies) (21-43) or conducted in controlled laboratory settings (44-50) and only recently has there been evidence from randomised clinical trials in healthcare settings (51-54).

Due to a paucity of level 1 evidence around the efficacy of facemasks/respirators, I hypothesised that around the world there would be varying policies and practices being implemented in regards to the use of facemasks/ respirators. This thesis aimed to examine the policies and practices around the use of facemasks/respirators for prevention of respiratory infections in healthcare settings, with a focus on low and middle income countries (hereinafter referred to as low resource countries).

Although various upper and lower respiratory infections occur in the healthcare setting, this research is primarily focusing on the following infectious threats: influenza (seasonal influenza, pandemic influenza and avian influenza), Severe Acute Respiratory Syndrome (SARS) and tuberculosis (TB). The rationale for selecting these particular threats is outlined in the introduction (chapter 1).

This thesis is made up of a series of studies conducted at different organisational levels:

1) Health department level

2) Hospital level

3) Staff level

This thesis is organised as follows:

Chapter 1 includes a review of the current literature and covers the following areas:

1. Epidemiology of nosocomial respiratory pathogens such as influenza, SARS and TB including a review of the agent, host and environment characteristics, disease burden amongst the general public and HCWs and mode of transmission.
2. Basic infection control strategies to control these three diseases, with a focus on Personal Protective Equipment (PPE).
3. The types of facemasks and respirators used in the health care setting and factors associated with their use
4. Issues associated with non-standard practices such as the reuse/extended use of facemasks and respirators.

Chapters 2 and 3 describe the results of the two studies conducted at the "health department level," which aimed to analyse the policies and guidelines around the use and re-use of facemasks and respirators. Publically available policies and guidelines from the World Health Organization (WHO), the US Centers for Disease Control and Prevention (CDC), and selected high and low/middle income counties have been analysed in Chapter

2. Chapter 3 contains the cross sectional survey that was conducted in three low/middle income countries to further elucidate the information collected during the review of policies and guidelines. The results of a survey conducted at "hospital level" to examine the practices around the use and re-use of facemasks and respirators are reported in Chapter 4.

Chapters 5 and 6 describe the results from two studies conducted at the "staff level". A qualitative study undertaken to examine the knowledge, attitudes, and practices of HCWs towards the use of facemasks and respirators is documented in Chapter 5, while the factors affecting the compliance of HCWs with the use of facemasks are described in Chapter 6. While undertaking the research, I identified a gap in the literature regarding the use of cloth masks. In Chapter 7, the available evidence around the efficacy and use of cloth masks has been reviewed. On the basis of these studies, I have developed a series of recommendations around the use of facemasks and respirators in low resource settings, which are presented in the last chapter. Table 1.1 provides a summary of each chapter, its constitution in the thesis and publication status.

Additional co-authored publications that are related to this thesis are presented in the appendices. These publications directly or indirectly support the findings of my studies and my work is extensively cited. CR MacIntyre and I conducted a "state of art review" around the use of facemasks and we contributed equally to writing this paper (55). A large RCT was conducted in Vietnam to examine efficacy of cloth masks and I contributed to statistical analysis and manuscript writing (56). Although the focus of my thesis was low/middle income countries, an Australian study provided additional data around facemasks use in high income countries for comparison. I contributed to data management and manuscript writing (57). The Ebola outbreak in West Africa provided additional opportunity to examine policies and practices regarding the facemasks use for diseases other than influenza, SARS and TB (58-60). As a second author, I significantly contributed to writing three papers around the selection and use of facemasks for Ebola.

Table 1.1: Summary of chapters

Chapter No	Chapter title	Organisational level	Aim and contribution to thesis	Publication status
1	Literature review		Provide context of the study	
2	Availability, consistency and evidence-base of policies and guidelines on the use of masks and respirators to protect hospital HCWs: a global analysis.	Health department	Policies and guidelines regarding the use of facemasks and respirators were critically analysed	***Published***
3	Examining the policies and guidelines around the use of masks and respirators by HCWs in China, Pakistan and Vietnam.	Health department	A multi-country survey was conducted to elucidate the information collected during the analysis of policies and guidelines	***Published***
4	Practices around the use of masks and respirators amongst hospital HCWs in three diverse populations.	Hospital	A multi-country survey was conducted in 89 hospitals to examine the translation of policy into practices	***American Journal of Infection Control (In press)***
5	Current practices and barriers to the use of facemasks and respirators among hospital-based HCWs in Vietnam.	Staff	Focus groups were conducted to examine knowledge, attitudes, risk perceptions and practices regarding the use of facemasks and respirators among hospital-based HCWs	***Published***
6	Factors affecting compliance of HCWs with the use of facemasks.	Staff	A study was conducted to examine compliance of HCWs with facemask use and factors associated with compliance	***Submitted***

			within the setting of a randomized controlled trial	
7	Use of cloth masks in the practice of infection control – evidence and policy gaps.		The evidence around efficacy of cloth masks was examined and various approaches were reviewed to try and improve the effectiveness of cloth masks	***Published***
8	Discussion and recommendations.		Discussed the implications of the results and proposed recommendations	

CHAPTER 1: LITERATURE REVIEW

INTRODUCTION

Through their work activities, hospital healthcare workers (HCWs) are exposed to a wide variety of hazards, including biological, chemical, physical and psychological stressors, but the most important threat is the exposure to infectious diseases. Infectious patients present to the hospital, transmit their infections not only to other hospitalized patients, but also to HCWs. Therefore, HCWs are at high risk not only for the acquisition of infections but also for transmitting respiratory, bloodborne and other infections (1-12). Laboratory-acquired infections are also common in HCWs (13-15).

According to the WHO, there are 12.5 million HCWs in the Asia Pacific region (61), many of whom are working in countries with ongoing threats such as avian influenza A (H5N1) virus and new threats such as Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and influenza A (H7N9). During a pandemic or outbreak of an unknown respiratory pathogen, preventing the transmission of pathogens is necessary for both HCWs and patients. In the initial period, the characteristics of the pathogen will not be known and a vaccine against the pathogen might not be available for many months or longer (62) and will likely be not available for everyone during the pandemic or outbreak (63, 64). In addition, some engineering controls (e.g. airborne infection isolation rooms) will be not feasible for in many settings. Therefore facemasks and respirators and other personal protective equipment (PPE) are considered as first line of defence against the infective organism in pandemic and outbreak situations and risk of infection increases if HCWs are exposed to the pathogen the without proper respiratory protection (65, 66). HCWs are at the front line and there is an occupational health and safety (OHS) obligation to protect them (58, 59). The discussion around OHS obligations has recently been renewed since the recent Ebola outbreaks in West Africa where more than 800 HCWs have died (58, 67).

While previous studies have documented that HCWs can be infected by a range of viral and bacterial infections, this literature review will focus on three occupational threats. Influenza (including seasonal influenza, avian influenza and pandemic influenza) was

selected as the primary infection of interest. Given the recent emergence of MERS-CoV, we felt that it was also important to examine respiratory protection practices used when dealing with an 'emerging infection'. Therefore, Severe Acute Respiratory Syndrome (SARS) was used as an example of an emerging infectious disease. Lastly, tuberculosis (TB) was selected as an example of a serious airborne infectious disease. In contrast to influenza and SARS, TB has long incubation and infectious periods.

Mode of disease transmission

Control of infectious diseases primarily depends on nature of pathogen, particularly the transmission mode. Following are the main transmission modes for infectious diseases:

Droplet transmission

In the current infection control paradigm, droplet transmission is defined as transmission via large particles (typically > 5 um) that do not suspend in the air (19, 68). Many viruses (e.g. influenza and coronavirus) and bacteria (e.g. *Streptococcus pneumoniae* and *Haemophilus influenzae*) are classified as being transmitted through the droplet mode (69-72). Droplet transmission requires close contact for transmission to occur. Close contact is defined as 1-2 meters (or 3-6 feet) in most guidelines. During coughing, sneezing, talking or therapeutic procedures (suctioning and bronchoscopy), pathogen-containing droplets expelled by the infectious person can be transferred to the mucus membranes of the susceptible person's nose, mouth or conjunctiva (19, 68).

Airborne transmission

Airborne transmission is defined as the dissemination of small pathogen-containing particles (typically < 5 um) or droplet nuclei in the air. Large particles (>20 µm) do not stay suspended in the air, however small particles (<5 µm), can remain suspended for long periods (19, 68). Face to face contact is not required for this mode of transmission, as some organisms can remain infectious while dispersing over long distances by air currents, causing infection in susceptible individuals at some distance from the source person. In

this case a single person may infect many people by coughing, as can occur in the case of measles, varicella, influenza and *Mycobacterium tuberculosis* (19, 68).

However, it has been suggested that the airborne/droplet transmission paradigm is based on outdated studies (73-76). Roy and Milton proposed that there are actually three types of aerosol transmission; i.e. obligate, preferential and opportunistic (77). Obligate transmission refers to an organism that only transmits via small particle aerosols in the natural setting, e.g. TB. In preferential transmission, aerosols are the primary mode of transmission, but natural infection may also occur via other routes. In some special conditions, organisms that are typically transmitted through other routes may be transmitted through small particle aerosols. This is called opportunistic transmission. For example, the primary modes of transmission of influenza and SARS are thought to be droplet and contact but they may also be transmitted through aerosol generating procedures (77).

Contact transmission

Contact transmission occurs through direct or indirect contact. Direct contact transmission occurs when microorganisms are transferred from one infected person to another person without a contaminated intermediate object or person, e.g. during contact with the contaminated hands or skin of the infectious person during patient care activities. Whereas indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object (fomite) or person. Respiratory syncytial virus (RSV), adenovirus and parainfluenza virus are primarily transmitted through the contact mode. Evidence shows that SARS, MERS and influenza may also be transmitted via fomites (68). However transmission depends on the ability of the virus to survive on the hand or surface in an adequate dose. Many environmental and surface factors affect the virus survivability, but currently the data are limited.

Debate around the transmission modes;

Currently there is a debate on the transmission mode of various pathogens and the relative significance of each mode is not clear (58, 78). Transmission of most pathogens is multimodal and current transmission studies are based on outdated experiments (73-76). There are other factors that should be considered when selecting appropriate infection control measures, such as uncertainty around transmission modes, high case fatality, the medical condition of HCWs and the availability of other treatment options (58). Droplet and airborne transmission may not be differentiated one the basis of particle size or distance from the source. Currently it is believed that respiratory protection is not required for droplet transmitting infections as particles are not inhaled. Studies show that particles of various sizes are produced during coughing, sneezing and medical procedures and can be inhaled by the people near the source (77).

Furthermore, “aerosol transmission,” which includes droplet and airborne transmission is less studied. “Aerosols” are tiny little particle and droplets which may suspend in the air (79). Respiratory aerosols are generated during AGP resulting in "aerosol transmission”, which may be different from classical "airborne transmission” in that although the pathogen is inhaled as in airborne transmission, transmission may occur only over short distances (73). “Airborne transmission” occurs in diseases that are transmitted over long distances (e.g. TB), whereas, “aerosol transmission” can occur in diseases transmitted more often through other routes but which may also be transmitted by respiratory aerosols, particularly during AGPs (e.g. influenza and SARS) (73). Infectious aerosol particles can travel short and long distance depending on particle size, humidity and other environmental conditions (80, 81). All these factors should be considered when considering transmission based precautions.

SECTION 1: EPIDEMIOLOGY OF INFLUENZA, SARS AND TB

EPIDEMIOLOGY OF INFLUENZA

Agent, host and environment characteristics

Influenza is an RNA virus from the family Orthomyxoviridae and has three types; A, B and C (82). Type A is further divided into many subtypes, based on presence of hemagglutinin (H) and neuraminidase (N) protein on the surface of the virus. 18 different hemagglutinin (H) and 11 different neuraminidase (N) surface proteins have been identified so far (82). Eight HA subtypes (H1, H2, H3, H5, H6, H7, H9, and H10) and six NA subtypes (N1, N2, N3, N7, N8 and N9) have been reported to infect humans to date (83). Influenza B only circulates amongst humans and is classified according to the lineages (84). Influenza C causes mild illness and generally does not cause epidemics (83).

Seasonal influenza

Epidemics of influenza A occur during the winter seasons in temperate countries due to the circulating strains. Currently influenza A (H1N1) and A (H3N2) subtypes are circulating among humans (85). Seasonal influenza is considered not to be as severe as pandemic influenza, because most people have some immunity against the circulating strains. The genetic properties of virus change due to “antigenic drift”, resulting in seasonal outbreaks. “Antigenic drift” causes minor changes in the genetic material and new strains are related to the already circulating strains (84, 86).

The average incubation period for influenza is two days (range 1-4 days), however it may be longer (up to 10 days) for the new strains (84, 87, 88). The serial interval (the mean interval between onsets of illness in two consecutive patients in a chain of transmission) is 2-4 days (84, 87, 88). Viral shedding starts 24-48 hours before symptom onset and reaches its peak during the first 24-72 hours of the illness. Shedding then declines and becomes low or undetectable by the 5^{th} day of illness. Around 30% to 50% seasonal influenza infections may be asymptomatic and will not result in clinical illness. Seasonal influenza

can cause more severe disease in very young, elderly, and immune-compromised individuals and as well as patients with lung and other chronic diseases (84, 87, 88).

Pandemic influenza

Pandemic influenza occurs due to the emergence of new strains to which people have little or no immunity. New strains of virus emerge due to "antigenic shift" and different HA and NA combinations are formed that have not circulated in humans before. (84, 86). Major changes occur in the surface protein when two different strains of virus infect a cell and a new type of virus emerged due to this re-assortment. Humans usually have no or very little immunity against the new virus, resulting in high morbidity and mortality (84, 86). Only influenza type A virus causes pandemics and the presence of H and N proteins determine the type of the virus and potential of the epidemic. Previous pandemics since 1900 were caused by the H1N1, H2N2 and H3N2 (82, 89-91).

Avian influenza

Avian species are the reservoir of influenza A virus and almost all strains (except H17N10 and H18N11) have been found in wild and/or domestic birds (92). Outbreaks of avian influenza occur sporadically in birds and humans in various geographical areas. Although many avian influenza viruses are circulating among the birds, few of them make the transfer to humans. Cases of H5N1, H7N7, H9N2 and H7N9 viruses have been reported in humans and H5N1 and H7N9 are currently circulating (93-95). Avian influenza viruses can be classified into highly pathogenic avian influenza (HPAI) virus and low pathogenic avian influenza (LPAI) virus on the basis of pathogenicity in chickens (95, 96). Avian influenza viruses generally have distinct characteristics, mode of spread and clinical outcomes (96).

Modes of transmission

Influenza is traditionally thought to be transmitted primarily via droplet and contact routes; however airborne/aerosol transmission has also been reported (84, 97, 98).

Ongoing debate about the transmission of influenza

There is a lot of discussion and debate about the primary mode of influenza transmission and the relative contribution or significance of other mechanisms (if any). Most of the information regarding the mode of transmission of influenza is based on old experiments, such as observational studies conducted during outbreaks or is based on research carried out for other purposes, for example drug and vaccine trials (64).

Droplet and contact are typically thought to be the main transmission modes for seasonal influenza (97, 99). Brankston et al systematically reviewed transmission studies and concluded that influenza virus is transmitted short distances and there is less evidence of airborne transmission (97). Contact transmission depends on amount of virus and type of surface; however it is largely undermined (16). Influenza viruses may survive on hard surfaces for 24–48 hours, on cloth up to 8–12 hours and on hands for up to 5 minutes (100).

However, some researchers argue that the evidence suggesting that droplet and contact are the main modes of transmission is not adequate and that there are now sufficient data available supporting the transmission of influenza via aerosolisation (98). Influenza viruses were isolated from aerosol samples collected during a study in an emergency department in the US in 2009 and more than half of the aerosols were of respirable size (49% 1-4 μm and 4% <1 μm) (101). A second study undertaken in a student health clinic by the same research group also reported influenza viruses (23% 1-4 μm and 42% < 4μm) in aerosol samples (102). Bischoff and colleagues collected air samples from a tertiary care hospital during 2010-2011 influenza season and reported that HCWs were infected by the small (<4.7μm) size particles. The study also reported that 19% of patients emitted more virus than others and that HCWs might be infected at up to a 6 foot distance from patients. (103). A recent study demonstrated that 80% and 82% of participants produced small virus-containing particles while breathing and coughing respectively (104). An

observational study in a commercial airplane (105), few animal (106-109) and modelling studies (110) and a systematic review (111) also support the aerosol transmission of influenza. It is also believed that influenza may be transmitted during aerosol generating procedures (AGPs); for example, intubation, suctioning and bronchoscopy (112). A nosocomial outbreak in Prince of Wales Hospital in Hong Kong in 2010 was attributed to aerosol transmission (113). However most of these studies failed to demonstrate clear evidence of aerosol transmission and many were not carried out in natural settings. In addition, some studies did not find evidence of influenza transmission through respiratory aerosols in such settings (114).

The different modes of transmission that are postulated to occur during seasonal influenza outbreaks versus pandemics have also been discussed in the literature, however definitive evidence is lacking. The pandemic influenza plan from the US Department Health and Human Services (HHS), states that the proportional contribution and clinical importance of the possible modes of transmission of influenza (i.e., droplet, airborne, and contact) remains unclear and may depend on the strains of virus ultimately responsible for a pandemic (112). However, an epidemiological study conducted during the 2009 pandemic on the transmission of H1N1 reported a lack of evidence around airborne transmission, however this may not rule out short-range aerosol transmission (115). Aerosol transmission of seasonal influenza (116) and pandemic influenza strains (117) have been reported in a guinea pig model. A ferret model also showed evidence of aerosol or droplet transmission of H1N1 (109, 118). .

Predominant modes of transmission may also depend on seasonal variation in temperate and tropical countries. Lowen and Palese hypothesised that aerosol transmission is the main mode of transmission during the winter season in temperate regions, while contact is the major mode of transmission in the tropics (119). However there is no scientific evidence in support of this hypothesis. As the mode of transmission of a microbial agent determines the infection control measures needed, understanding the modes of transmission of influenza is important in choosing appropriate PPE.

Disease burden

Seasonal influenza

The burden of seasonal influenza may not be estimated precisely due to subclinical or asymptomatic infection and non-reporting of influenza like illness (ILI) cases (120). In addition, some surveillance studies have been based on laboratory diagnosis while others have been based on clinical symptoms. Approximately three to five million cases of seasonal influenza are thought to occur globally every year and among those around 0.25 to 0.5 million people die (85, 121). Kuster and colleagues conducted a meta-analysis of influenza studies and reported that incidence rates of symptomatic (serology positive) influenza were 5.12% and 3.04% in un-vaccinated and vaccinated adults, respectively (122). Compared to the general public, corresponding rates were higher in un-vaccinated (7.54%) and vaccinated (4.81%) HCWs (122).

In the US, influenza causes approximately 36,000 excess deaths and nearly 226,000 excess hospitalizations annually (123, 124). Every year around 75,000 people in Canada are admitted to hospitals with influenza and 6,700 of them die (125). More than 300,000 GP consultation and 8000 hospitalizations in Australia are attributed to influenza (126). Although fewer data are available from low and middle income countries, a high influenza burden has been reported from existing studies. The annual incidence rate of influenza in Thailand is reported to be 6% (5,941/100,000) (127). A systematic review on the seasonal influenza epidemiology in sub-Saharan Africa showed that amongst the patients who sought treatment for the acute respiratory infection (ARI), 1–25% of illnesses were caused by influenza (mean 9·5%) and 0·6–15·6% (mean 6·6%) of children admitted to hospital for ARI were diagnosed with influenza (128). Approximately 25% of the children admitted through the emergency department in a regional hospital in Hong Kong were reported to have an ILI (129). Influenza surveillance data from Pakistan show that laboratory confirmed influenza is detected in around 20% of the samples collected from five sentinel

sites (130). In Vietnam, influenza virus was detected in around 22% of the patients with ILI who presented to 15 sentinel sites (131).

Pandemic influenza

Four influenza pandemics have occurred since the start of the 20th century. The Spanish Influenza or 1918 pandemic was due to H1N1, and was responsible for around 40 million deaths globally (89). While the 1957 pandemic, caused by an H2N2 virus, killed an estimated two million (82) and the 1968 pandemic (caused by H3N2 virus) killed around one million people worldwide (90). In 2009, influenza A(H1N1)pdm09 virus emerged in Mexico and spread worldwide (132). Unlike past pandemics, the 2009 pandemic was considered not to be that serious (no worse than a bad seasonal influenza season), which may have been due to partial immunity amongst some members of the community due to prior exposure to similar strains. As of November 2009, approximately 622,482 cases and 7826 deaths had been reported due to influenza A(H1N1)pdm09 virus from 207 countries (133). By the end of August 2010, influenza A(H1N1)pdm09 virus had spread to 214 countries and the reported death toll was 18,449 (134). In Australia, around 37,000 laboratory confirmed cases and 200 deaths were reported (135). As of August, 2010, China had reported 128,033 confirmed cases and 805 deaths (136). The available data suggest that 262 confirmed cases were reported from Pakistan (137) and 321 confirmed cases were reported from Vietnam (138). However these numbers are based on the laboratory confirmed cases reported to the WHO and are probably an underestimate. In France, 13,942 cases per 100,000 population of self-defined influenza were reported during H1N1 outbreak (139). According to the CDC, around 61 million cases of influenza A(H1N1)pdm09 virus occurred between April 2009 to April 2010 in the US alone, with approximately 274,000 hospitalizations and 12,470 deaths (140).

During a pandemic, HCWs are on the frontline of the response and may also become a potential source for disease spread (62). A study during the influenza A (H1N1)pdm09 pandemic showed that around 2.2% HCWs (328/15,018) were infected during the

pandemic (5). However this was based on self-reported cases and may not include asymptomatic infections. Another survey in Thailand during the pandemic reported serological evidence of virus in 13% (33/256) of the HCWs tested (65). Most of these cases were expected to have been exposed in the healthcare setting, although exposure from the community cannot be ruled out (141). HCWs may also transmit influenza to patients during routine care (142, 143). A review of nosocomial influenza outbreaks from 1959-1994 showed that despite underreporting, HCW to patient transmission was suspected in 5 out of 17 hospital outbreaks (143).

Avian influenza (H5N1)

Since 2003, the WHO has reported 650 confirmed human cases of avian influenza from 15 countries (144). Most cases and deaths were reported from Indonesia (cases 197, deaths 165), Egypt (cases 177, deaths 63), Vietnam (cases 127, deaths 64), Cambodia (cases 56, deaths 37) and China (cases 47, deaths 30) (144). H7N9 also recently emerged from China and the number of reported cases has been increasing steadily (96).

EPIDEMIOLOGY OF SEVERE ACUTE RESPIRATORY SYNDROME (SARS)

Agent, host and environment characteristics

SARS associated coronavirus (SARS-CoV) is an enveloped, single strand RNA virus (68, 145, 146) and is known to cause infection in both humans and animals (147). Like other zoonotic infections, SARS emerged due to close association between human and animals. SARS-CoV is believed to be an animal virus that crossed the species barrier to humans due to ecological and human behaviour changes (148). The virus is stable in faeces and urine of infected cases for 1-2 days at room temperature and up to 4 days in the faeces of the diarrheal cases. The virus may survive on formica surfaces for up to 36 hours, on plastic and stainless steel for up to 72 hours and on glass slides for up to 96 hours (149). The mean incubation period of SARS-CoV is 4-6 days (Range 2 to 10 days) (149).

The virus first emerged from the Guangdong Province, in Southern China, in November 2002 (150) and became a global threat in March 2003 (151). The serial interval of SARS in Canada and Singapore was 10 to 11 days during the initial phase of outbreak and decreased to 7-8 days following control measures (152). Peak infectivity occurs after two weeks of illness. The basic reproduction number (R_O, the mean number of secondary cases generated by one infected person in fully susceptible population) of the SARS-associated coronavirus was 2-4 (152). The majority of cases of SARS during the 2002-03 epidemic were adults. Children were less affected and had milder disease (153). The average case-fatality ratio (CFR) of SARS-CoV was estimated to be around 10% (7).

Mode of transmission

Direct contact (with mucus membranes) and droplets are considered to be the main modes of transmission of SARS-CoV (68). Indirect contact with fomites may also lead to infection, as the virus can survive on environmental surfaces for a long period (68). Contact with the body fluids and faeces of SARS patients may also lead to transmission. Some aerosol generating procedures enhanced SARS transmission, particularly tracheal

intubation (154). Although the data on faecal-oral transmission were not convincing, caution was recommended (152).

Whether the virus can spread via the airborne or other routes is still not known (145). The SARS outbreak in the Amoy Garden Housing Complex in Hong Kong (156) and in a hospital in China (157) provide some evidence of the airborne transmission of SARS. The risk may increase during AGPs and other high risk procedures due to production of more respiratory aerosols. A systematic review showed that the risk of SARS might increase during AGPs, for example, tracheal intubation, non-invasive ventilation and tracheotomy (154). Another study in Canada reported a high rate of SARS among the HCWs performing endotracheal intubation (158). However there are some conflicting results as well. According to one study, high risk procedures may not be associated with the SARS after adjustment for the incorrect or inappropriate use of PPE is made (25).

Another unique aspect of SARS transmission is “super spreading events”. This means the transmission by infective cases is not uniform and an individual case, called a “super spreader” may spread disease to many healthy people (152, 159, 160).

Disease burden

According to WHO, the 2002-03 SARS outbreak affected 29 countries and led to 8,096 probable cases and 774 deaths (7). Most cases were reported from China (n=5327), Hong Kong (n=1755), Taiwan (n=346), Canada (n=251) and Singapore (n=238). Health care facilities were the most common source of the SARS CoV transmission (145). Among the total 8096 SARS cases, 1706 (21%) were HCWs. In some countries, the percentage of infected HCWs among total cases was extremely high. For example, out of a total of 63 SARS cases in Vietnam, 36 (57%) were HCWs. Similarly the proportion of HCWs, among the total SARS cases, was also high in Canada (43%), Singapore (41%), Hong Kong (22%), Taiwan (20%) and China (19%) (7). According to WHO, the last case of SARS was reported on 5 July 2003. Although a few cases occurred later in 2003 and 2004, they were due to breaches in laboratory bio-safety and sporadic community-acquired infection. Fortunately,

significant secondary transmission did not occur (151). Since 2004, no new cases of SARS-CoV have been reported anywhere in the world. However in 2012, a novel coronavirus, Middle East respiratory syndrome coronavirus (MERS-CoV), emerged in the Middle East and spread to the UK and to a few other countries (161-163). To date, 699 laboratory confirmed cases of MERS-CoV and 209 deaths have been reported to the WHO (164).

EPIDEMIOLOGY OF *MYCOBACTERIUM TUBERCULOSIS* (TB)

Agent, host and environment characteristics

TB is a highly contagious disease caused by the bacterium, *Mycobacterium tuberculosis*. It is a rod shaped microbe, which usually infects the lungs (165). In high prevalence countries, young adults in their most productive years are most at risk (166). Most TB cases occur in low income countries due to poverty and weak economic conditions. TB is one of the three leading causes of death among women of reproductive age; with approximately 500,000 women dying of TB annually (167). It is the second leading cause of death due to single infectious agent (168). The natural history of TB is complicated due to the various stages between exposure and development of clinical disease. Among exposed cases, only about 10-30% will be infected and currently around one third of the world population is infected with TB (168). Among the infected cases around 10% percent develop disease during their lifetime (99, 167).

Mode of transmission

TB is an airborne infection and spreads through inhalation of aerosols containing TB bacillus (99, 165). Many human and animal studies have reported airborne transmission of *Mycobacterium tuberculosis* (169, 170).

Disease burden

According to the WHO, approximately 9 million new TB cases occur every year (including 1.1 million cases among people living with HIV) and among those, around half are smear positive (166). Most of these cases occur in Asian and African countries (166). The worldwide prevalence of TB is 12 million (range 11-13 million). Around 1.5 million people die due to TB every year and 95% of deaths occur in developing countries (166). China, Pakistan and Vietnam are listed among the 22 high burden TB counties. The incidence of TB is very high in China where around 1.1 million new TB cases occur every year. In

Pakistan and Vietnam, 650,000 and 160,000 new TB cases respectively occur every year and the prevalence in the three countries is much higher than this (166).

Multi drug resistant TB (MDR-TB) is a form of TB caused by bacteria that are resistant to two major anti-tuberculosis drugs, i.e. isoniazid and rifampicin (171). The proportion of the MDR-TB in new or secondary treatment TB cases is around 3.5% and 20.5%, respectively. The global prevalence of MDR TB cases is around 650,000 and 480,000 new cases of MDR-TB occur every year (167). Bacteria that are resistant to isoniazid and rifampicin (MDR-TB), any floroquinolone and any of the second line anti TB injectable drugs (i.e. amikacin, kanamycin and/or capreomycin) cause extensively drug resistant TB (XDR-TB). Currently very limited data are available regarding the burden of XDR-TB (171) and it is estimated that 9% of MDR-TB cases have XDR-TB (167).

Many studies report an increased rate of TB infection among HCWs (6, 172-176), particularly amongst those exposed to a large number of TB patients or amongst HCWs reported to have been involved in autopsies and high risk AGPs (177). Factors including the number of TB patients examined, job characteristics and place of work, delay in diagnostic suspicion, patients with MDR-TB strains, limited access to appropriate ventilation systems, non-compliance with aerosol dissemination precautions, immune suppression and malnutrition are important risk factors for TB infection among HCWs (178, 179). HCWs in the HIV-endemic areas are even at more risk of MDR-TB or XDR-TB infection (180).

SECTION 2: INFECTION CONTROL STRATEGIES

Under the occupational health and safety obligations employers are responsible to provide a safe work place for their employees. As HCWs are at increased risk of acquiring infections, the hospital environment should be safe and various infection control strategies should be adopted to prevent transfer of infections to HCWs (181, 182). Infection control strategies are categorised in the literature in a number of ways:

1. The hierarchy of infection control
2. Pharmaceutical and non-pharmaceutical measures
3. Standard and transmission based precautions

THE HIERARCHY OF INFECTION CONTROL

Infection control strategies are categorised according to three levels of hierarchy (16, 19);

1. Administrative controls: Development of policies, procedures and the implementation of various strategies (e.g. assigning responsibilities, risk assessment, source control, education and training).
2. Engineering and environmental controls: Aimed at reducing the spread of infections through various isolation and air exchange measures. For example: proper ventilation, establishing airborne infection isolation rooms, developing systems for cleaning and waste disposal and designing appropriate PPE.
3. Use of appropriate personal protective equipment (183): Gloves, gowns, aprons, facemasks/respirators etc. These measures are implemented at the individual level.

Administrative and environmental controls are important to control influenza (particularly pandemic influenza), SARS and TB. PPE is considered lowest in the infection control

hierarchy and is recommended in combination with administrative and environmental controls. However, PPE become the first line of defence during outbreaks and pandemics when the transmission mode is unclear and vaccines are unavailable.

PHARMACEUTICAL AND NON-PHARMACEUTICAL MEASURES

Infection control measures are also categorised in the literature as pharmaceutical and non-pharmaceutical. Pharmaceutical measures refer to the use of vaccines, antivirals and antibiotics. Influenza vaccines provide varying levels of protection depending on age, immune status and type of vaccine (184). According to a recent systematic review, the overall efficacy of inactivated influenza vaccine is 60% (95% CI 53% to 66%) (185). The efficacy of trivalent inactivated vaccine (in adults) and live attenuated vaccine (in children) is 59% (95% CI 51-67) and 83% (95% CI 65-91), respectively (187). Influenza vaccine also prevent complications, hospitalization, deaths, particularly in elderly persons (188).

Considering the fact that approximately one-third of influenza cases can be asymptomatic and community exposure cannot be avoided, the use of vaccine is considered a cost-effective strategy to protect HCWs from seasonal influenza (189). However, vaccine uptake is typically reported to be low among HCWs (190). In comparison, BCG vaccine has low efficacy against pulmonary TB and protects mainly against severe forms of the disease in children, like TB meningitis and miliary TB (191). Antiviral drugs such as oseletamivir (Tamiflu) or Relenza may be good for influenza prophylaxis but not for SARS. Anti TB drugs are available for both prophylaxis and treatment of TB disease. It is unlikely that low income countries will be able to access sufficient drugs to protect their HCWs, therefore other mechanisms are required.

Non pharmaceutical measures include the use of PPE, isolation, quarantine, social distancing and adoption of hygienic measures (63, 64, 192). These measures may be effective against transmission of these respiratory infections. A multi-faceted approach using a combination of the various infection control strategies is recommended to

decrease transmission of infectious diseases in healthcare settings; including PPE, triage, isolation and vaccination (16, 19).

STANDARD AND TRANSMISSION BASED PRECAUTIONS

Standard and transmission based precautions are recommended for the control of infectious diseases in healthcare settings. Standard precautions are utilised during routine work in healthcare settings to prevent the transmission of infections (16). In some instances, the aetiology of the diseases may not be established, which may lead to spread of infection. Standard precautions are not sufficient in this case. Presence or absence of an infective case does not matter, because standard precautions are based on assumption that blood, all body fluids, excretions, secretions, non-intact skin and mucus membranes are infective, until proved otherwise. Standard precautions include: using appropriate PPE, ensuring hand hygiene, respiratory/ cough etiquette, safe injection practices and adoption of standard operating procedures to handle and disinfect patient care equipment and other utilities, including waste management (16, 19).

Transmission based precautions are used for those patients who have or are suspected to have an infectious disease. Transmission based precautions depend on the characteristics of organism, for example agent, host, environment and modes of transmission. Modes of transmission are particularly important as prevention measures depend on transmission mode; for contact, hand hygiene, for droplet, facemasks and for aerosols, respirators. In some cases, like newly emerging infections and pandemics, transmission based precautions will be used empirically till the organism is identified and the mode of transmission is confirmed. As mentioned above, the main modes of respiratory disease transmission are contact, droplet and airborne. Precautions for contact transmission are the use of gloves and gowns, dedicated equipment, limiting patient movement, separation of infectious cases and careful transportation. Maintaining a spatial separation (>3 feet or 1 meter) and use of proper masks are the main transmission based precautions for droplet spread infections. Finally, transmission based precautions for airborne infections include

isolating patients in airborne infection isolation rooms (AIIR), adopting a respiratory protection program (including using respirators) and a restriction on visitors (16, 19).

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Various types of PPE have been in use for decades for the prevention of infection. PPE use is highly recommended by WHO, OSHA, CDC and other agencies, for the prevention of the infections in health care settings (16, 19, 62, 183). PPE is a special type of clothing or equipment worn by workers for protection against health and safety hazards. The National Academies recommend that PPE should effectively reduce risks of disease or injury to HCWs, have a minimum effect on patients, be acceptable and usable by HCWs, be cost-effective and easy to use (183). PPE includes the use of facemasks, respirators, gloves, eye protection, face shields, gowns and head and shoe coverings (183). Although controversies prevail regarding the efficacy of various PPE, the need for planning and preparation, training, availability and accountability is obvious.

VARIOUS TYPES OF PPE

The selection of PPE primarily depends on the nature of patient interaction and mode of transmission of the disease to be prevented (19), however many other factors also play a role, such as risk perception, severity of infection, pre-existing medical illness and cost (58).

Gloves

Gloves are used to prevent the transfer of microorganisms from contaminated surfaces to the hands. The use of gloves is recommended when there is a risk of contact with blood and body fluids, including respiratory secretions. Gloves are single use and hand hygiene should be done after glove removal. Evidence suggests that transmission of pathogens can occur from contaminated hands and other surfaces (193). An outbreak in a nursing home in Hawaii provides some evidence of transmission though contaminated hands and fomites (193). Bean and colleagues also reported survival of influenza virus on hard

nonporous surfaces for 24-48 hours and cloth, paper, and tissues for less than 8-12 hours (100). In the case of influenza, gloves are recommended if there is potential for exposure to respiratory secretions (e.g. during aerosol generating procedures) and if pandemic influenza is associated with diarrhoea (112). Gloves are strongly recommended for prevention of SARS infection (152), however, gloves may have no role in protection from TB.

Gowns

Disposable or washable gowns are used to avoid soiling of the clothes with blood and body secretions. Gowns prevent contamination of clothes, which may lead to transferring of microorganisms from one area to another area. Disposable or washable gowns are used to avoid soiling of clothes with blood and body secretions. Gowns are not recommended as a measure to prevent influenza in general, except during certain procedures such as intubation and resuscitation (112). However, gowns are recommended if the outbreak of influenza is also associated with diarrhoea (112) and in the case where some new emerging infection is suspected, e.g. SARS (194).

Goggles and face shields

Goggles and face shields are used to protect HCWs from transmission of microorganisms into the eyes from the contaminated hands or the transfer of infection from the eyes to others. Trans-ocular transmission of influenza is not well established. Therefore the use of goggles and face shields is not recommended for influenza, expect to avoid sprays or splashes of infective material (112). In studies conducted, there is some evidence that trans-ocular transmission of influenza may occur and transmission of influenza may be reduced further if eye protection is used with respiratory protection (195). Conjunctivitis associated with H7N7 avian influenza infection reported in the Netherlands also suggests that transmission may occur through the conjunctiva (196). Eye protection is recommended for the prevention of transmission of SARS virus as well (194).

Facemasks and respirators

Facemasks (medical and cloth masks) and respirators are the most common PPE used to prevent the spread of the respiratory droplets and aerosols. Various types of facemasks are being used in the health care setting for the protection of HCWs and patients, ranging from medical masks, cloth masks, paper masks and respirators. Respirators are either disposable (filtering face piece respirators) or reusable (elastomeric respirators or powered air purifying respirators) and have different filtration efficacies, i.e. N95, N99 and N100 (197, 198). The main difference between facemasks and respirators is the intended use. Generally, facemasks are used by HCWs and patients to prevent the spread of infections to each other while respirators are used to protect the wearer (19). Facemasks and other physical barriers are good at protecting the mucosa of the nose and mouth from splash and spray of blood and body fluids and containing the emissions of the wearer, while more precautions are required for pathogens that can be inhaled and cause infection. A combination of administrative measures (e.g., restricting visitors, educating patients and staff, and cohorting HCWs assigned to an outbreak unit), environmental measures (e.g. isolation) and PPE (facemasks and respirators) are recommended to decrease transmission of influenza in the health care settings (199). Facemasks and respirators will be discussed in detail in next section.

ROLE OF PPE IN VARIOUS INFECTIONS

Influenza

PPE is used as part of standard and transmission based precautions to protect HCWs from seasonal influenza (16). PPE is particularly important during the early stages of an outbreak or pandemic, when the mode of transmission and virulence characteristics are uncertain, and when pharmaceutical measures; such as vaccines and antivirals, may not be available. However, the use of PPE alone may not be sufficient and should be implemented with other strategies (16, 19). Like other infectious disease control programs, standard and transmission based precautions have been recommended for

dealing with pandemic influenza patients as well. After a literature review and expert panel discussion, Aledort and colleagues concluded that hand hygiene, rapid viral diagnosis, PPE and isolation in the health care setting are effective strategies during pandemics, however, evidence is lacking for the effectiveness of PPE for the general public, closure of schools and workplaces and mandatory social distancing (192).

SARS

Gamage et al performed a systematic review of the efficacy of PPE in preventing the transmission of e) versus respiratory infections, including SARS (200). Gamage and colleagues also reviewed various studies carried out during the SARS outbreak and concluded that failure to implement appropriate barrier precautions resulted in more healthcare associated infections (201). The use of PPE was increased during the SARS outbreak and was found to be effective in preventing transmission of hospital acquired infections (202, 203). Around 11,092,000 surgical masks, 758,000 gowns, 2,954,000 pairs of latex gloves and 21,000 shoe covers were distributed in Beijing alone (204). A study in Taiwan during the SARS outbreak, reported that PPE use might reduce the viral load in infected HCWs, resulting in a reduction in secondary transmission (203). Compliant use of PPE was associated with low rate of SARS among HCWs in Hong Kong (205) and Singapore (206).

TB

The use of PPE in TB has mainly been discussed in relation to the use of facemasks and respirators. Combining the use of administrative and environmental control measures, with PPE has been found to be more effective than PPE alone (207-209).

Issues with various PPE

There are many issues with the use of PPE; however the main issues are proper use, compliance and availability. HCWs need to be trained on how to use PPE properly to minimise the risk of infection. The evidence suggests that HCWs are not compliant with

the use of various types of PPEs (210, 211). Wearing a facemask is considered “the most bothersome” (212) and compliance with the use of facial protective devices is reported to be the lowest compared to other PPE (213-215). A review suggests that compliance with the use of facemasks ranges from 4% to 55% (mean 30%) (216). The availability of PPE is also important to ensure use and it is also a predictor of compliance (216, 217).

Many issues have been recently highlighted regarding the selection and use of PPE during the Ebola outbreaks in West Africa. (58-60). Ebola virus is primarily transmitted through direct contact with blood and body fluids, therefore most health organisations and countries initially recommended a medical mask with face shield to protect HCWs (60). However, the recommendations were subsequently changed in favour of respirators and full body suits due to HCW infections and increased risk perception and to comply with occupational health and safety obligations (60).

SECTION 3: USE OF FACEMASKS/ RESPIRATORS IN HEALTHCARE SETTING

TYPES OF FACEMASKS/RESPIRATORS

The following are the most common types of respiratory protection used in the health care setting:

1. **Facemasks**
    a. Medical masks (surgical masks, procedure masks, laser masks, isolation masks, dental masks)
    b. Cloth masks (cotton masks, gauze masks, homemade masks, woven masks)
    c. Paper masks
2. **Respirators**
    a. Air purifying or particulate respirators
        i. Disposable or filtering piece respirators
        ii. Reusable or elastomeric respirators
        iii. Powered air purifying respirators
    b. Air supplying or atmosphere-supplying respirators
        i. Self-contained breathing apparatus
        ii. Airline respirators

MEDICAL MASKS

Health organizations and countries use various terms when referring to medical masks. The WHO frequently uses the term “medical masks” (16), while CDC mostly uses the term “facemask” (17, 218). The US National Academy of Sciences uses the term “medical masks”; which includes surgical and procedure masks (197), while the US Food and Drug Administration (FDA), includes laser, isolation, dental or medical procedure masks with or without a face shield under the category of ‘surgical masks’ (219). The Australian Department of Health and Aging (220) and the US Occupational Safety and Health Administration (OSHA) uses the term “surgical masks” in their pandemic preparation plans (62). Regardless of the classification, the terms “medical masks” and “surgical masks” are most commonly used in the health care setting. Medical/surgical masks (hereinafter medical masks) are defined as “masks that provide protection against pathogens carried by large respiratory droplets that can contaminate the mucous membranes” (221).

Types and shapes of medical masks

Medical masks are available in two shapes: flat-pleated or duck-billed and pre-moulded. Flat-peaked or duck-billed shaped medical masks are adjusted to the bridge of the nose with a flexible metal piece and are attached to the head with two ties. Pre-moulded medical masks are adjusted to the bridge of the nose and attached to the head with a single elastic string (197). Some medical masks (mainly procedure masks) have flat-peaked or duck-billed shapes and have ear loops.

Structure and regulation

Medical masks are generally made of a three ply structure of non-woven material, usually polypropylene (197, 219), spun-bonded, melt-blown or wet-laid (219). Filtration through the mask material is by mechanical impaction, however a significant amount of air can leak between the mask and face as well. Medical masks are considered to be a medical device, thus testing for respiratory protection is not required (222). In the US, FDA

regulates the use of medical masks and reviews the testing data provided by manufacturers (510 K submission) to approve for marketing. Mask manufacturing companies are required to provide a description of the product, including material used, specification and dimensions, style and design features (219). The European standard for the regulation of medical masks (EN 14683:2005) requires the manufacturers to perform testing and "self- certify" the device for EC approval under the Medical Devices Directive (93/42/EEC) (223). In Australia, medical masks are required to meet Australia Standard AS 4381 (224).

Types of the medical masks (Pictures are removed due to copy right)

Figure 1.1: Standard tie on medical masks

Figure 1.2: Standard ear loop medical masks

Figure 1.3: Duck bill medical masks

Figure 1.4: Moulded cone medical masks

General use

(Note: Information regarding the efficacy of facemasks against influenza, SARS and TB will be discussed in detail in the next section)

Medical masks are used for three purposes in the health care setting (16, 19, 183):

1. Operating theatre: Medical masks are used by HCWs in the operating theatre to reduce the transfer of potentially infectious body fluids in sterile areas.

2. Source control: Medical masks are also used by coughing (or infective) patients to prevent spread of infection.

3. Respiratory protection: Medical masks are used by HCWs to protect from splashes of blood and body fluids.

<u>Operating theatre</u>

The traditional use of medical masks is in operating theatres (OTs) to prevent infections at surgical sites. However, the effectiveness of medical masks in preventing surgical site infections is yet to be proven. Many historical studies have showed that facemasks do not prevent surgical site infections. In 2014, Lipp and Edwards recently conducted a systematic review and reported low efficacy of facemasks against surgical site infections (225). The rate of surgical site infections was even higher in the masked group than the control group in some of these studies (226-228). Laslett and Sabin evaluated the use of medical masks and surgical caps in 504 patients undergoing percutaneous heart

catheterization. They concluded that medical masks and surgical caps were not necessary to prevent infections during heart catheterization (229). In a hospital based study, facemasks were not used during approximately 1000 surgical operations and there was no increase in the infection rate compared to the infection rate in the previous five years in the same hospital (226). Tunevall conducted a large clinical trial in 1991 and examined the rates of post-operative infections in patients operated on by “masked” and “unmasked” surgical teams. The rate of surgical site infection was 3.5% (73/1537) in the no mask group compared to 4.7% (55/1551) in the mask group. The authors concluded that the use of facemasks may protect the surgical team from acquiring infections but may not prevent surgical site infections (228). Experimental studies have also demonstrated that small amounts of oral bacteria dispersed during normal breathing may not contaminate the operating field and the use of facemasks may not be necessary in the OT subject to the availability of proper ventilation (227).

In contrast to this, the results of other studies support the use of medical masks in OTs. Chamberlain and Houang started a randomized control trial in women having gynaecological surgery. The trial had to be discontinued in the initial phase because the rate of wound infection was found to be higher without mask use (230). Alwitry et al attempted to measure the amount of bacteria that fell on the operative field during cataract surgery by placing culture plates near patients’ heads. The amount of bacteria that fell on the operative field was significantly lower when the surgeon used a medical mask, compared to when the surgeon did not use a mask (231).

Source control

Medical masks are also used by coughing patients to prevent spreading of infection to people around them. Medical masks are commonly recommended for pulmonary TB patients to prevent the spread of TB to people around them (20). Dharmadhikari and colleagues checked the rate of infection in guinea pigs, which breathed the air coming from the wards of multi drug resistant TB (MDR-TB) patients. The patients were grouped

into “mask” and “no mask” groups and tuberculin skin test (TST) conversion rates were then observed amongst the guinea pigs. The rates of infection in guinea pigs when patients used and did not use masks were 40% and 76.6% respectively and the authors concluded that the risk of TB transmission might be reduced by 56% if the patients used a mask (232).

Medical masks are also recommended to prevent spread of influenza from the wearer (183). In an experimental study, Johnson and colleagues reported that both medical masks and N95 respirators prevent the spread of influenza virus from the wearer (233). Milton and colleagues collected samples of "fine" and “coarse” exhaled particles from 37 influenza cases, before and after using medical masks. Wearing a medical mask was associated with 2.8 fold reduction in the shedding of “fine” viral aerosols and a 25 fold reduction in shedding of “coarse” viral aerosols (an overall 3.4 fold reduction, 95% CI 1.8 to 6.3) (234).

Medical masks for respiratory protection

Despite the fact that medical masks have been used for the prevention of respiratory infections for a long time, their role in respiratory protection is much debated. In some guidance documents, medical masks are even not included in the list of PPE (183). The main reasons are that medical masks are not designed to provide respiratory protection and they have consistently lower filtration efficiency than respirators, which varies according to the material used (46, 50, 235). Even high filtration efficacy masks will not be protective unless there is a good seal to the face and masks are not built to have a good facial seal. Laboratory studies have also demonstrated that medical masks have a lower filter efficiency (ranging from 10% to 90%) (236) and a lower capacity to remove sub-micrometer-size bio-aerosols (237, 238). Rengasamy et al tested five types of FDA cleared medical masks for particle penetration and found them to have various filtration capacities (i.e. 7.5-76.3% at 85 liters/minute constant flow rates) (239). Even multiple medical masks worn at the same time were found to be less protective than US National

Institute for Occupational Safety and Health (NIOSH) certified respirators in a study of healthy volunteers. In a crossover trial, healthy volunteers wore single, double and multiple medical masks and filtration performance was measured. The median reduction in the particle count inside the masks was 2.7 fold with one mask and 5.5 fold with five masks, which is far less than the reduction with a respirator (240).

However, medical masks may protect HCWs from infection acquired through splashes and sprays of blood and body fluids. There is some evidence that medical mask may also protect HCWs from droplet transmitted infections, clinical respiratory illness (CRI) and influenza like illness (ILI), though they are less effective than a respirator (22, 50, 53, 54). The role of medical masks for the prevention of contact transmission is not clear, however they may prevent contaminated hands touching the face (241). Compared to respirators, medical masks are cheaper, easier to wear, fit testing is not required and they can be used by men with facial hair (242).

CLOTH MASKS

(Note: Further information about cloth masks is contained in Chapter 7)

In the early 19th century cloth masks were used in OTs to prevent the spread of infections from the surgeon to the patient (243, 244). The first study on cloth mask use by HCWs was published in 1918. Weaver observed low rates of diphtheria and scarlet fever in hospital HCWs who used a cloth mask compared to the period when they did not use a mask (245). During the same period, masks were used to protect from scarlet fever, measles, influenza, plague and TB (246-250). Cloth masks were used in hospitals for TB prevention during the 1930s and 1940s (250, 251). It was also reported that cloth masks were used during SARS and other outbreaks in China and Vietnam (58, 204, 252, 253). However, there has been much less research around the use of cloth masks since the development of disposable medical masks in the mid-20th century (254, 255). Most cloth mask studies are observational or in-vivo and to date no control trial has been published to examine the efficacy of cloth masks in the health care setting.

Material used and regulation

Cloth masks are commonly made of cotton, gauze, or silk. No regulations exist for cloth masks as they are mainly used in low resource countries (256).

Various types of cloth masks (Pictures are removed due to copy right)

Figure 1.5: Tie on cotton mask

Figure 1.6: Cotton mask with ear loop

Figure 1.7: Gauze mask

General use

Currently, there is a lack of sufficient information about cloth masks to either support or refute their effectiveness in blocking the transmission of infections (197). Laboratory studies have demonstrated that cloth masks may provide some protection, but much less than a respirator or a medical mask (46, 257). Although the efficacy of cloth masks is yet to be proved, some health organisations recommend their use if respirators and medical masks are not available (197, 258-260). In a guidance document "Reusability of Facemasks during an Influenza Pandemic" by the Institute of Medicine of the National Academy of Sciences, the members were hesitant to discourage the use of cloth masks despite acknowledging a lack of efficacy data and the risk of infection to the wearer (197). Similarly in a position paper, the US Association for Professionals in Infection Control and Epidemiology (APIC) also considered the use of cloth masks during pandemics in case of a shortage of medical masks and respirators (259). In the infection control guidelines for "Viral Haemorrhagic Fevers in the African Health Care Setting", both the WHO and CDC

recommend using cloth masks if respirators or medical masks are not available (260). It has been argued that cloth masks may be the only option for low resource countries, which may not be able to afford respirators or medical masks. It has also been suggested that HCWs who report adverse effects (i.e. skin reactions) associated with the long use of respirators could use cloth masks as an alternative (261).

Cloth masks are generally comfortable to wear because they are permeable to air, resulting in less breathing and skin problems; however low filtration capacity against respiratory droplets and aerosols could be a challenge. Because it is not clear that cloth masks or improvised masks can meet the standards set by regulatory bodies and without better testing and more research, cloth masks or improvised masks generally have not been recommended as effective respiratory protection devices or as devices that would prevent exposure to splashes or sprays of blood or body fluids (197). In addition, respiratory protection may not be ensured by the inexperienced users of the cloth masks. There is a concern that the use of cloth masks may give users a false sense of protection that will encourage risk taking and/or decrease attention to other hygiene measures (45, 197).

PAPER MASKS

Paper masks are a type of facemask with single layer of wood pulp or other material. Paper masks are generally not recommended in the health care setting, however they are commonly used in low resource countries. Paper masks were used in Hong Kong during the SARS outbreak, however they were found to not be effective as they were easily wet with saliva (22).

Figure 1.8 Paper masks **(Picture is removed due to copy right)**

RESPIRATORS

Respirator are defined as “respiratory filtering devices that provide protection against inhalation of small and large airborne particles” (221). According to OHSA, a “respirator is a device that protects from inhaling dangerous substances, such as chemicals and infectious particles” (262).

Types and shapes of respirator

Common types of respirators used in the health care setting are: 1) air-purifying or particulate respirators and 2) air-supplying or atmosphere-supplying respirators. Air-purifying respirators are further categorized into filtering face piece (FFP) or disposable respirators, elastomeric or reusable respirators and powered air-purifying respirators (PAPRs) (262). FFP respirators come in various shapes, for example, cup, duckbill and moulded. Reusable or elastomeric respirators are either full face or half face. Air-supplying respirators provide the highest degree of respiratory protection and are used to avoid inhalation of very hazardous environmental substances. Common types of air-supplying respirators are self-contained breathing apparatuses and airline respirators (62, 197, 262).

Air purifying respirators are commonly used in the health care setting and are classified into three series (N, R and P) depending on their ability to resist oil. The “N” means not resistant to oil, the “R” means somewhat resistant to oil and the “P” means strongly resistant to oil (i.e. oil proof) (62, 262). Three efficiency levels (i.e. 95%, 99%, and 99.97%) exist for N, R and P series, thus making a total of nine different types. “N” series respirators are tested with sodium chloride aerosols while “R” and “P” series are tested with oil based aerosols. The assigned protection factor (APF) is calculated by estimating the ratio of the number of particles outside the respirator to number of particles inside the respirator (62, 262).

Structure and filtration mechanism

FFP respirators are completely made of the filter material and are single use. The filters are typically made of polypropylene wool felt or fiberglass paper (62, 262, 263). Elastomeric respirators are reusable and have two parts: face piece and cartridge. The face piece of elastomeric respirators is either of full face or half face, and made of rubber, neoprene, silicone or plastic. Silicone is usually preferred because it is comfortable, flexible and easy to wash. The face piece of the elastomeric respirators may be cleaned and reused, however its cartridge is discarded and replaced (62, 262, 263).

FFP respirators and elastomeric respirators are non-powered; instead the wearer draws air in through the filter or cartridge, creating negative pressure inside the respirator. Some respirators also have exhalation valve, so negative pressure is not created inside. Breathing is improved as valves are opened during the exhalation. However respirators with exhalation valves should not be used when there are chances of spreading an infection from the wearer (62, 262). In this case a surgical respirator may be a better choice. PAPRs have a battery system, which is used to pull contaminated air through the filter piece. It uses a HEPA filter, which is the equivalent of 100 filters, to protect the wearer against airborne infections, and is used during AGPs, e.g. intubation, suctioning and bronchoscopy. Fit testing is not required for PAPRs and they can be used by men with facial hair (62, 262). PAPRs are much more comfortable that FFP respirators and can generally be tolerated much longer. Battery time is generally long and indicated in case of low battery. However, PAPRs must be cleaned when used to protect against pathogens that can be spread by contact and batteries need to be replaced.

Respirators work through various mechanisms; including filtering hazardous particles from the air, removing contaminants with chemicals and supplying clean air from outside (262). The filtration process is mainly used for FFP and elastomeric respirators, and it is different for large and small particles. Large particles do not pass through the filter media and collide with the respirator fibre and may be captured by interception, sedimentation and

inertial impaction. Small particles may pass the fibre filter through diffusion. As particle size decreases, the diffusive capacity of particles increases due to temperature. Electrostatic capture of the charged particles is another filtration mechanism, which facilitates interception and diffusion as well. Chemical decontamination is the method used by gas mask respirators (62, 262). Air supplying respirators supply clean air from outside.

Regulation

In the US, NIOSH regulates the testing and certification of respiratory protection equipment (263). NIOSH tests filters for the effects of loading particle burden, temperature, and relative humidity and requires a minimum filtration efficiency of 95%, 99% or 100%. Filters can be certified for a range of efficiency classes (e.g. 95%, 99% or 100%) as well as for their ability to withstand degradation as a result of loading or oil mist exposures. N95 filters cannot allow more than 5% of the challenge aerosol concentration to penetrate the filter, and would be expected to have less aerosol penetration with either larger or smaller particles than the size used in certification testing (183, 197). In Europe, European Norm (EN) standards are followed for testing respirators. Respirators need to be marked with 'Conformité Européen' (CE), which means that the respirator meets the criteria of EN certification (264). Various types of the filtering face piece respirators used in Europe are: FFP1, FFP2 and FFP3, which meet minimum filtration efficiencies of 80, 94 and 99%, respectively (265). FFP1, FFP2, and FFP3 are equivalent to NIOSH certified N95, N99 and N100 respirators. In Australia, AS/NZS 1716 standard regulates respirator use. P2 is equivalent to the N95 respirator (266).

Various types of respirators (Pictures are removed due to copy right)

Figure 1.9: Filtering face piece N95 respirator

Figure 1.10: Elastomeric respirators

Figure 1.11: Powered air purifying respirator (PAPR)

General use

Properly fitted respirators are designed to fit tightly to the face and have been found to provide better protection against airborne and droplet infections compared with medical masks (46, 53, 54, 235, 267). FFP are commonly recommended for airborne infections (e.g. TB) (18, 20, 268) and high-risk procedures (e.g. AGPs) in health care settings (16, 269). Elastomeric respirators (re-useable full face respirators with changeable cartridges)

are increasingly being used in the health care setting and simulated studies have shown that they offer better protection compared to the disposable N95 respirator (270). CDC also recommends the use of powered air purifying respirators (PAPRs) when performing high risk procedures on TB and Ebola patients (20, 271). PAPRs were also recommended and used during the SARS outbreak in Canada (272).

Some studies have suggested that respirators should be used to protect from exposure to "surgical smoke", which is an aerosol generated in surgery due to a laser or diathermy (273, 274). The use of fit tested respirators is recommended in OTs to prevent inhalation of infective material from the surgical site which may include certain micro-organisms and may be harmful to surgical team (275). Researchers argue that the use of surgical masks may only prevent exposure to splashes of blood/ body fluids during the operation and OT staff should use a respirator to protect themselves from infective aerosols generated by modern surgical technologies (275).

The main problem with the use of respirators is the direct cost of the products and the indirect cost of implementing comprehensive respiratory protection programs including training and fit testing. Low compliance levels are another problem associated with the use of respirators, as is the occurrence of adverse effects linked with respirator use (53).

Fit checking and fit testing

Respirators come in various sizes and designs to fit a range of face shapes and to prevent leakage around the respirator from occurring. Fit checking and fit testing are important components of respirator use.

- Fit checking (or user seal check) is different from fit testing and is necessary to ensure that respirators fit the face and are properly sealed (276). Fit checking should be done every time a HCW dons an N95 respirator and both positive and negative pressure should be checked (276).

- Fit testing is very important to ensure the efficacy of respirators and even certified respirators do not provide the same level of protection (270, 277). In the qualitative fit test, Bitrex™, saccharin or irritant smoke is released into a chamber and the wearer tastes or smells these agents (278). The qualitative test is used to check the leakage around the face, however it does not quantify the amount of leakage. Air sampling is performed from inside the respirator in quantitative testing and amount of leakage is calculated though a fit testing instrument (278).

However, hospitals may not comply with fit testing requirements and HCWs generally do not comply with fit checking procedures. A California study undertaken during the influenza A (H1N1)pdm09 showed that HCWs performed a fit check after donning a respirator only in 20% (3/15) of observations (279). A survey of the members of Society for Healthcare Epidemiology of America (SHEA) showed that less than one third of hospitals fit-tested their employees before the start of the influenza A (H1N1)pdm09 pandemic (280). Lastly, another study showed that approximately one third of the HCWs infected with influenza A (H1N1)pdm09 in the US were never fit-tested (141). However, very limited data is available from low and middle income countries.

Fit checking or testing is not needed for PAPRs and due this reason some hospitals choose PAPRs precisely. They are also more protective than FFP respirators.

OTHER TYPES OF MASKS

Other types of masks are also recommended and used in health care settings. Dust masks are used at some facilities, however they are not regulated and their particle filtration efficacy is less compared to fit-tested N95 respirators (281). Some medical masks and respirators have been coated with nano-materials (antibacterial), however to date the efficacy has not been tested (282). New types of facemasks are also being tested in health care settings. A respirator made of plastic with a disposable filter was compared to an N95 respirator, however the results were not promising due to low filtration performance of the plastic respirator compared to the N95 respirator (283). Medical masks made of

charcoal (carbon) layers are also being used in health care sector. Lastly, Improvised and homemade cloth masks are widely used but there is a lack of evidence about their efficacy.

Table 1.2: Difference between commonly used facemasks and respirators used in health care setting

	Medical masks	Cloth masks	N95 respirators
Nomenclature	Surgical masks, procedure masks, laser masks, isolation masks, dental masks	Cotton masks (gauze masks, homemade masks or woven masks)	Disposable or filtering face piece respirators
Material used	Polypropylene or sometimes spun-bonded or melt-blown	Mostly cotton or gauze	Polypropylene or fibre glass paper
Sizes	Usually one size	Range of sizes	Range of sizes in some models
Intention to use	Used by coughing (or infectious) patients to prevent spreading of infection. Used by HCWs to reduce transfer of potentially infectious body fluids in a sterile area (e.g. OT). Used by HCWs to protect from splashes of blood and body fluids.	Used by coughing (or infective) patients to prevent spreading of infection. Used by HCWs to reduce transfer of potentially infectious body fluids in a sterile area (e.g. OT). Used by HCWs to protect from splashes of blood and body fluids.	For protection from respiratory infections, particularly airborne infections
Filtration capacity	Protect from large particles, i.e. > 100 microns	Protect from large particles, i.e. > 100 microns	Protect from small particles, i.e. < 100 microns
Facial fit	Surgical masks are not designed to seal the area between the mask and the face. A gap remains between the mask and face and air will pass through the gap.	Cloth masks are not designed to seal the area between the mask and the face. A gap remains between the mask and face and air will pass through the gap.	Seals to the face of wearer so there is no gap between the respirator and face, so most of the air passes through the filter.
Fit testing	Not required	Not required	Required
Fit (User seal)	Not required	Not required	Required

check			
Filtration mechanism	Mechanical impaction	Mechanical impaction	Large particles are captured by interception, sedimentation and inertia. Diffusion and electrostatic capture is for small particles.
Regulations	In the US, FDA review data provided by the manufacturers (510 K submission) and approve for marketing. In Europe manufacturers perform testing and self-certify medical masks for use.	No regulations	In US tested and certified by the NIOSH under regulation 42 CFR 84 In Europe, European Norm (EN) standards are followed for testing respirators. In Australia, AS/ NZS 1716 standard regulates the respirator use
Test protocols	Particle filtration efficacy, bacterial filtration efficacy, fluid resistance and flammability testing.	No testing protocols	Filtration efficacy Total Inward Leakage
Extended use	Subject to considerations of hygiene, damage, and increased breathing resistance. No RCT data available for extended use.	Subject to considerations of hygiene, damage, and increased breathing resistance. No data available for extended use.	Subject to considerations of hygiene, damage, and increased breathing resistance. Use may extend beyond 8 hours only if it is demonstrated that extended use will not degrade filter efficiency and total mass loading of filter is less than 200 mg.
Reuse after decontamination	Not recommended	Various decontamination techniques are applied	Not recommended
Advantages	Protect against droplet infection, easy to use, few side effects (less breathing difficulty and skin reactions) Low cost	May protect against droplet infection, easy to use, few side effects (less breathing difficulty and skin reactions) Low cost and reuse possible (but not tested)	Protect against both droplet and airborne infections Fit to face so no air leak, air passes through filter media
Disadvantages	May not protect against airborne	Efficacy not proved	Communication problems, mainly with

	infections Does not fit tightly to the face, so air leaks between the face and the mask	Does not fit tightly to the face, so air leaks between the face and the mask	elastomeric and PAPR Some leakage may occur into the face piece even in best circumstances Need training for use and fit testing Low air permeability may lead to skin reaction and difficult breathing in FFP and elastomeric respirator. High cost

Source: Adopted from Institute of Medicine (IOM) National Academy of Sciences. Reusability of Facemasks During an Influenza Pandemic: Facing the Flu.

EFFICACY OF FACEMASKS AND RESPIRATORS

Most research in infection prevention and control has focused on pharmaceutical interventions. The largest body of research on non-pharmaceutical measures has been on hand washing (284-286). Up until recently there had been a paucity of high quality studies of masks and PPE, with most evidence coming from lower quality case control (21-27), cross sectional (28-33), observational (34-43) and in-vivo (44-50) studies carried out during outbreak and pandemics. These studies generally examined the combined effect of PPE and other infection control measures; therefore making it difficult to determine the effectiveness of facemasks and respirators (25).

To date, only four clinical trials have been conducted to examine the role of facemasks/respirators in the health care setting (51-54). Three systematic reviews have also been published on the role of facemasks and respirators (235, 287, 288) and there have been six other reviews on facemasks and other PPE interventions (192, 200, 201, 289-291).

Efficacy against seasonal influenza

All RCTs in the health care setting have been underpowered to determine the efficacy of facemasks/respirators against laboratory confirmed influenza or ILI (51-54). Of the trials, only one (the smallest of all) included a control arm while the other three RCTs (52-54) compared the efficacy of medical masks and N95 respirators. The efficacy of medical masks/N95 respirators cannot be proved without a control arm as both arms may be equally effective or ineffective. Although one clinical trial (53) included a convenience control arm, the data were excluded from primary analysis.

The first clinical trial was conducted in Japan in 2008 and randomised HCWs to one of two arms: medical mask and control. It was a small trial (n=32) and was underpowered to determine the efficacy of medical masks against upper respiratory infection (URI). The rate of URI was the same in the intervention and control arms (51). However, self-

reported symptoms were recorded in this study and laboratory diagnosis was not undertaken. A second clinical trial was conducted in Canada during the same year and randomised 466 nurses into one of two arms: medical masks and N95 respirators. The rate of laboratory confirmed influenza was not significantly different between the intervention arms (medical masks 23.6% and respirator 22.9%, risk difference, −0.73%, 95% CI, −8.8%-7.3%). The authors concluded that both medical masks and respirators are equally effective (52). Given the absence of a control arm and high rate of influenza in both arms, both arms might be equally ineffective (55). Further, the study is probably underpowered for the outcome of influenza, with the possibility of misclassification of influenza, given that the majority of outcomes defined as "influenza" were classified on the basis of serological positivity, without exclusion of vaccinated subjects (who may also mount a serological response) (52, 53).

MacIntyre and colleagues conducted two large cluster randomised trials in China in 2008-09 and 2009-10 (53, 54). In the first trial, 1922 HCWs were randomised into medical mask, fit-tested N95 and non fit-tested N95 arms. Given the high rate of mask use in China, it was deemed unethical to randomise HCWs to a control arm. Instead a convenience control arm was included which included HCWs who reported low rates of mask use. However, the data for the control arm were excluded from the primary analysis (53). Compared to the medical mask arm, the rates of all outcomes were consistently low in the N95 arms, however only CRI was significantly low in the non-fit-tested N95 arm (OR 0.48, 95% CI 0.24-0.98). When compared to the convenience control arm, rates of CRI (OR 0.36, 95% CI 0.14–0.94) and laboratory confirmed influenza (OR 0.33, 95% CI 0.12–0.89) was lower in the non-fit-tested N95 arm. As the rate of fit-test failure was very low, authors also analysed the data by combining two N95 arms (i.e. non-fit tested and fit tested). The rates of CRI (OR 0.38, 95% CI 0.17-0.86) and laboratory-confirmed viral infection (OR 0.19, 95% CI 0.05-0.67) were significantly lower in the N95 group compared to the medical mask group (53). In the second RCT, MacIntyre and colleagues randomised 1669 HCWs into three arms, (i) continuous use of N95 respirators, (ii) targeted use of N95 respirators while doing high-risk procedures and (iii) continuous use of medical masks. Continuous

use of N95 respirators was associated with a lower risk of CRI (HR 0.39, 95% CI 0.21–0.71) and bacterial colonisation (HR 0.40, 95% CI 0.21–0.73) (54). The efficacy of N95 respirators against laboratory confirmed influenza was not proven in any trial due to the low rates of influenza.

Most observational studies around the use of facemasks were conducted during the SARS outbreak and very few studies have examined the role of facemasks against influenza. A hospital based survey in Hong Kong reported that 23% of HCWs developed ILI symptoms despite using a facemask, which was attributed to low influenza vaccine uptake and suboptimal adherence to PPE during high risk procedures (28). A case control study showed a high rate of influenza and other viral infections (serological evidence) amongst dental surgeons who used facemasks, compared to the controls (p value <0.001) (29). Another case control study undertaken during a Hajj medical mission also failed to prove the effectiveness of facemasks, with no reported differences in ARI rates between masked (16.4%) and unmasked (22.2%) HCWs (OR 1.5, 95% CI 10.4 to 5.6) (21).

Systematic reviews of PPE and facemasks (192, 200, 201, 235, 287-291) have included observational studies and earlier RCTs (51, 52), but have not included larger, more recent RCTs (53, 54, 292). While acknowledging a lack of high quality studies, most reviews recommended the use of facemasks in general. Cowling and colleagues reviewed 12 studies, including two RCTs in health care settings and four RCTs in the community setting. They reported a lack of data and evidence around the efficacy of facemasks in both health care and community settings (287). Gralton and McLaws reviewed facemask studies to inform selection between surgical masks or respirators and concluded that most studies in health care settings were of medium to low quality and were inconclusive (235). Bin-Reza and colleagues conducted a systematic review of facemask studies (including three RCTS in health care settings and five RCTs in community settings) to provide recommendations around facemask use during the influenza A (H1N1)pdm09 pandemic. The authors concluded that most studies were inconclusive and did not provide evidence of the efficacy of facemasks and/or respirators against influenza (288).

Efficacy against pandemic influenza

The use of facemasks/respirators is considered an effective prevention strategy during pandemic influenza, though evidence is lacking. Historical data show that the number of influenza cases continued to rise during the 1918 influenza pandemic, despite cloth and cotton masks being regularly used by HCWs and the general public (293-296). A study in Hong Kong during the influenza A (H1N1)pdm09 pandemic concluded that wearing a medical mask was protective. However this was a quasi-experimental study and other risk factors were not controlled (297). An observational study in Singapore also reported low rates of influenza A (H1N1)pdm09 among HCWs who used medical masks or respirators (43).

To add another layer of complication, studies conducted during outbreaks or pandemics may not be applicable to seasonal influenza due to the novelty of the pathogen, uncertainty around the mode of transmission and unusual high levels of compliance driven by heightened risk concerns.

Efficacy against SARS

The studies conducted on the use of masks and respirators during SARS generated mixed results, however most studies favoured the use of medical masks and/or respirators to reduce the risk of SARS infection among HCWs (22-27, 31-34, 37-40, 157). Seto et al conducted a case control study in five Hong Kong hospitals and reported that both facemasks and respirators were protective against SARS (p value <0.001) (22). A study in Vietnam reported high transmission of SARS in hospitals where facemasks were not used (OR 12.6, 95% CI 2.0 to 80) (26). However, Nicolle argued that the outbreak in Vietnam was contained without high level infection control measures such as negative pressure rooms and N95 respirators, and medical masks were considered sufficient (298). Wearing either a facemask or a respirator was associated with a low rate of infection among HCWs in Singapore (OR 0.1, 95% CI 0.02 to 0.86) (24) and Canada (RR 0.23, 95% CI 0.07 to 0.78) (34). Finally a study in Taiwan during SARS outbreak showed low viral load in

nasopharyngeal swabs of HCWs (24.36 ± 15.84 copies/mL) compared to non-HCWs (4346 ± 3246 copies/mL). The authors concluded that that facemask use might reduce viral load in HCWs, resulting in low morbidity and mortality, less secondary transmission and few long term complications (203).

However facemasks and respirators were found not to be protective against SARS in some studies as well (25, 32, 33, 39). Interestingly, a study in the US reported 110 HCWs exposed to SARS patients, of whom 45 (44%) did not use a medical mask or respirator. No case of SARS was reported in those 45 HCWs (32). Of 73 HCWs exposed to initial SARS cases in Taiwan, around half did not use any mask/respirator and were not infected (33).

A study in Hong Kong also failed to find a difference in the use of N95 respirators between SARS cases and controls (p value 0.168). However masks and respirators were found protective when combined with other PPE (p value < 0.001) (25). Similarly, a low rate of infection was reported from a public hospital in Vietnam, despite the fact that N95s were unavailable in initial period of outbreak and other control measures were applied (299).

Efficacy against TB

HCWs have been using various kinds of cloth and medical masks to protect from TB for many years (222, 250). Respirators were first recommended by the CDC for TB in 1990 (300) and before that, medical masks were commonly used by the HCWs in US hospitals (41). In 1994, the CDC published the "Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities" and strongly recommended the use of respirators by all HCWs exposed to TB patients. For high risk procedures, the CDC recommended enhancing protection by using more efficient respirators, PAPRs or air supplying respirators (301). The CDC also recommended implementing respiratory protection programs that had been already developed by NIOSH in 1987 (263). NIOSH published a respiratory protection program administrator's guide for TB in 1999. The main components of the NIOSH TB respiratory protection program are; conducting a TB risk assessment, selecting an appropriate respirator, ensuring availability of standard

operating procedures, medical screening of workers, training on use, face-seal, fit testing and fit checking, respirator inspection, cleaning, maintenance, storage and finally periodic evaluation of the program (302).

Many observational studies have reported low rates of TB infection among HCWs with the use of facemasks and/or respirators. However most of these studies examined the combined effect of administrative/environmental control measures and PPE use (42, 50, 207-209, 222, 303). Therefore, the low infection rate in HCWs may be attributed to other infection control measures and the efficacy of facemasks and respirators for TB prevention may still be unproven and other infection control strategies may be sufficient. For example, the rate of tuberculin skin test (TST) conversion in HCWs was measured in a hospital in New York (41) and Chicago (304), after improving compliance with infection control policies. The results showed a decrease in TST conversion in HCWs, even before the introduction of respirators. Respiratory protection programs were also found not to be a cost-effective strategy in a hospital in Virginia (305). In most US hospitals, administrative and environmental measures were found useful in reducing the risk of TB transmission to HCWs (41, 304, 305).

The WHO Policy on TB Infection Control also states that “the available evidence, although weak and indirect, generally favors respirator use for protecting the wearer from TB” (18). To the best of our knowledge, the advantage of facemask or respirator use alone for TB prevention in HCWs, has never been studied in natural settings. Most studies have either been observational, program evaluations, in-vivo or carried out in animals. Some researchers have tried to investigate the use of facemasks alone in absence of other interventions though modelling studies. Fennelly modelled the risk of TB infection according to various risk levels and reported low benefits of using respirators if proper ventilation was ensured. Respirators were found effective when the risk of aerolisation was high and PAPRs were recommended in such situations (222). In another modelling study, Basu and colleagues evaluated the role of various infection control measures in prevention of XDR-TB. The authors concluded that in the absence of administrative and

environmental controls, respirator use by HCWs and mask use by the patients may prevent only 5% of XDR TB cases (306).

SECTION 4: RE-USE OF FACEMASKS AND RESPIRATORS

To date there has been very little discussion about the re-use of facemasks and respirators in the literature. For the purpose of this research, the 're-use' of facemasks/respirators is divided into two categories:

1. Extended use: The use of a facemask or respirator by the same wearer for an extended time period or for the treatment of multiple patients, i.e. to use for more than one shift or day. The product is not decontaminated.

2. Re-use after decontamination: The process of decontaminating a mask or respirator for re-use by the same or different wearer on subsequent days.

These definitions have been used for the purpose of this study only and are based on observations from the field. According to CDC, extended use refers to "the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters" (307). The CDC defines re-use as "the practice of using the same N95 respirator for multiple encounters with patients but removing it ('doffing') after each encounter" (307). Medical masks and respirators are generally re-used for multiple times in low/middle income countries, with or without doffing after each encounter (308), therefore, the CDC definitions of "extended use" and "re-use" were grouped into "extended use" in this study. As cloth masks (occasionally medical masks and respirators as well) are commonly re-used in low resource countries after washing (308), a separate category of "re-use after decontamination" was created.

Currently, single use of medical masks and FFP respirators is recommended, but this is not always feasible. During a pandemic or extended outbreak, medical masks and FFP respirators may not be available for everyone. According to WHO estimates, approximately 233 million outpatient visits, 5.2 million hospital admissions and 7.4 million deaths will occur globally within a very short period if a new pandemic begins (309). CDC

estimated that approximately 1.5 billion facemasks and 90 million respirators would be needed by the health sector and around 1.1 billion masks would be needed by the public for a six week pandemic influenza outbreak (310).

Therefore CDC and other health organisations have considered the extended use and re-use of medical masks and respirators during outbreaks, pandemics and other high demand situations (62, 197, 307). However, the outer surface of medical masks or respirators may be contaminated and could be a source of infection (183, 311). The number of viral particles and length of survival are important factors to consider in case re-use is deemed essential (183). Mask manufacturers generally recommend single use of medical masks and filtering piece respirators and they may not be interested in testing the reusability of masks and respirators due to financial and legal implications (197).

Extended use of facemasks and respirators

Disposable medical masks and respirators have limited life spans and can become deformed, damaged or may become ineffective after single use. In addition, constant use and moisture may lead to difficulty in breathing (197). Currently data are lacking regarding the time period that the same mask or respirator may be continuously be used for. Available data suggest that respirators may be used intermittently or continuously for around eight hours (312) and adverse effects of facemasks increase with more than eight hours use (313).

Extended use of medical masks and respirators may become necessary in some situations. It has been suggested that extended use of facemasks is fine as long as the mask is not wet, soiled or damaged. However there are currently no clinical studies supporting this practice (62, 258). Considering the high demand for respirators during pandemics, OSHA recommends the extended use of respirators, if they are not soiled or damaged and are still functioning properly. Facemasks and respirators should be kept in a safe place and the product should only be used by the same wearer (62). During the SARS outbreaks, Health Canada advised medical masks and respirators could be reused if SARS was ruled out. In

case of exposure to a confirmed SARS case; reuse of contaminated masks and respirators was discouraged (314). WHO advised HCWs to use respirators for an extended period for TB protection, if the respirators are properly stored (315). Extended use should be balanced against the risk of infection and the wearer should not remove facemasks between patient encounters to avoid self-contamination (307).

Re-use of the facemasks and respirators after decontamination

Decontamination of medical masks and filtering piece respirators is usually not feasible because the materials of these products degrade with standard means of disinfection. Various decontamination methods have been studied to date, including: autoclave, isopropyl alcohol, bleach, hydrogen peroxide, microwave, soap and water, ultraviolet radiation and dry heat (197). The reuse of N95 respirators has been studied by Viscusi and colleagues in various studies (311, 316). In the first study (2007), they tested 10 chemical and non-chemical decontamination methods and among those hydrogen peroxide and UV germicidal irradiation (UVGI) caused the least changes in the filtration performance (316). In the second study (2009), they tested five methods for decontamination of N95 filtering face piece respirators: UVGI, ethylene oxide, vaporized hydrogen peroxide, microwave oven irradiation and bleach. UVGI, ethylene oxide and vaporized hydrogen peroxide were proven to be more effective methods than others. All three methods did not cause much physical change in the respirators; however the throughput capabilities of ethylene oxide and vaporized hydrogen peroxide were not confirmed (311). Similarly Lore and colleagues tested UVGI, microwave-generated steam (MGS), and moist heat (MH) for decontamination of the filtering face-piece respirators and found these methods effective in reducing viral load (317).

Respirators with a separate filtering piece (elastomeric respirators) are reusable, however the face piece needs to be cleaned and the cartridge replaced. Disposable or elastomeric respirators may be good in the case of high demand during pandemics (183, 197). OSHA recommends that NIOSH-certified elastomeric respirators can be used in situations when

the re-use of respirators is required (62). OSHA has provided guidelines for cleaning and disinfection of respirators, which include; disassembling (i.e. removing of filters, cartridges, or canisters), cleaning with warm water and disinfection with detergent or disinfectant approved by the respirator manufacturer, rinsing and drying; and reassembling. Filters, cartridges, and canisters are replaced or repaired where necessary. Finally the respirator needs to be tested to ensure that all components work properly (198). The National Academy of Sciences has proposed that decontamination methods must meet the following criteria: (1) the method must remove the viral threat, (2) be harmless to the user, and (3) not compromise the integrity of the various elements of the respirator (197). Powered air purifying respirators should also be cleaned and disinfected after use. The instructions of the respirator manufacturer should be followed so that the agent used for the decontamination does not damage the respirator (318).

Decontamination of the cloth masks

In an earlier guidance document, WHO recommended the sterilization and reuse of cloth masks by TB patients to prevent the spread of infection by coughing and sneezing, if medical masks are not available (315). In the Infection Control Guideline for Viral Haemorrhagic Fevers in the African Health Care Setting, CDC also recommends that cloth masks may be reused if they are not contaminated, dirty or torn (260). WHO discouraged mask use in the community setting during the influenza A (H1N1)pdm09 pandemic due to lack of evidence, however, the option of use and reuse of various types of cloth masks was discussed. In the case of cotton masks, WHO advised that they be washed with household detergent after use (319).

Other considerations for re-use of medical masks and respirators

Many other options are discussed in the literature in regards to the re-use of facemasks and respirators. In case of shortage, health care facilities are recommended to minimise the use of respirators through improving engineering and administrative control measures and prioritising the use of respirators for high risk situations (312). Few researchers have

discussed the combined use of both surgical masks and respirators to enhance efficacy, however adverse effects may be increased due to difficult breathing (320, 321). IOM has recommended wearing medical masks over the N95 respirators to extend the life of the respirator by avoiding surface contamination (183). Although N95 respirators may be used for a longer period, the practice may result in increased adverse events and risk of self-contamination.

CONCLUSION

Facemasks and respirators are commonly recommended and used to protect HCWs from acquiring nosocomial infections, and often are the only available protective measure during epidemics of emerging infections. The main difference between the two products is the intended use. Facemasks are used to prevent HCWs acquiring infections from splashes of blood and body fluids and to reduce the transfer of potentially infectious body fluids in a sterile area such as an OT. They are also used by coughing patients to try and prevent the spread of infections. However, facemasks were not designed to provide respiratory protection and they have consistently lower filtration efficiency than respirators. In comparison, a respirator is a device that protects the wearer against the inhalation of small and large airborne particles, that is, it protects the wearer from others who are or might be infected.

However, the efficacy of facemasks and respirators is still being debated in the literature. Most facemask studies are observational and were carried out during SARS and other outbreaks. To date only four clinical trials have been conducted in the health care setting to evaluate the efficacy of facemasks and respirators. The extent to which cloth masks are currently being used in is not possible to gauge, as the available data are very limited. There is also a paucity of high quality studies around extended use and re-use of facemasks and respirators. However, based on anecdotal information, it is believed that these practices are widespread in low resource countries. To date, there has been little work done examining the policies and practices around the use and re-use of facemasks/respirators in health care settings in low/middle income settings.

Due to a paucity of high quality evidence and lack of evidence around extended use/reuse practices, I hypothesised that health organisations and countries might have various policies and practices around the use of facemasks and respirators. This research is focused on understanding policies, practices and barriers around the use of respiratory

protection by HCWs in low resource settings. The specific research questions for this thesis include:

1. Do health organizations and countries have varying policies and guidelines around the use of facemasks and respirators?
2. Do hospitals follow national infection control policies and guidelines for use and re-use of facemasks?
3. What types of facemasks are being used at the hospital level?
4. What are the practices and perceptions of hospital-based HCWs regarding the use of facemasks and respirators?
5. Which factors are associated with compliance and use of facemasks among hospital-based HCWs?

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CHAPTER 2: AVAILABILITY, CONSISTENCY AND EVIDENCE-BASE OF POLICIES AND GUIDELINES ON THE USE OF MASK AND RESPIRATOR TO PROTECT HOSPITAL HEALTH CARE WORKERS: A GLOBAL ANALYSIS

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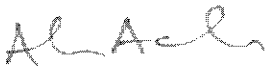
Declaration

I certify that this publication was a direct result of my research towards this PhD, and that reproduction in this thesis does not breach copyright regulations.

Abrar Ahmad Chughtai (Candidate): 

RATIONALE OF THE STUDY

The review of literature shows a paucity of high quality evidence around the efficacy of facemasks and respirators in health care settings. Most studies are observational and to date only 4 RCTs have been conducted to examine the efficacy of facemasks and/or respirators. Moreover, a few studies examined the policies and practices regarding the re-use of facemasks and respirators. Due to a lack of high quality evidence, I hypothesised that health care organisations and countries might have various policies and guidelines regarding the use and re-use of facemasks and respirators. In this study, I examined infection control policies and guidelines of selected health care organisations and countries to describe areas of consistency and inconsistency, as well as gaps.

Research question:

Do health organizations and countries have varying policies and guidelines around the use of facemasks and respirators?

CONTRIBUTION TO THE THESIS

This study highlights a significant variation in recommendations regarding the use of facemasks and respirators in health care settings. Many gaps were identified in the policy documents such as a lack of guidance on regulations, training and fit testing for respirator use; re-use of facemasks/respirators and use of cloth masks. The results contributed to the development of health department and hospital surveys (chapters 3 and 4). Insight gained from this study also helped in the development of recommendations around the use of facemasks and respirators in health care settings in low resource settings (chapter 8).

ABSTRACT

Background

Currently there is an ongoing debate and limited evidence on the use of masks and respirators for the prevention of respiratory infections in health care workers (HCWs). This study aimed to examine available policies and guidelines around the use of masks and respirators by HCWs and to describe areas of consistency between guidelines, as well as gaps in the recommendations, with reference to the WHO and the CDC guidelines.

Methods

Policies and guidelines related to mask and respirator use for the prevention of influenza, SARS and TB were examined. Guidelines from the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), three high-income countries and six low/middle-income countries were selected.

Results

Uniform recommendations are made by the WHO and the CDC in regards to protecting HCWs against seasonal influenza (a mask for low risk situations and a respirator for high risk situations) and TB (use of a respirator). However, for pandemic influenza and SARS, the WHO recommends mask use in low risk and respirators in high risk situations, whereas, the CDC recommends respirators in both low and high risk situations. Amongst the nine countries reviewed, there are variations in the recommendations for all three diseases. While, some countries align with the WHO recommendations, others align with those made by the CDC. The choice of respirator and the level of filtering ability vary amongst the guidelines and the different diseases. Lastly, none of the policies discuss reuse, extended use or the use of cloth masks.

Conclusion

Currently, there are significant variations in the policies and recommendations around mask and respirator use for protection against influenza, SARS and TB. These differences may reflect the scarcity of level-one evidence available to inform policy development. The lack of any guidelines on the use of cloth masks, despite widespread use in many low and middle-income countries, remains a policy gap. Health organizations and countries should jointly evaluate the available evidence, prioritize research to inform evidence gaps, and develop consistent policy on mask and respirator use in the health care setting.

Acronyms: Abrar Ahmad Chughtai (AAC), Holly Seale (HS) and C Raina MacIntyre (CRM)

INTRODUCTION

To maintain the functionality and capacity of the health care workforce during outbreaks or pandemics of emerging infections, such as influenza, health care workers (HCWs) need to be protected. Medical masks ("masks") and respirators are commonly used to protect HCWs from respiratory infections. In the health care setting, masks are used to prevent HCWs acquiring respiratory infections, from splashes of blood and body fluids and to reduce transfer of potentially infectious body fluids in a sterile area. Alternatively, they may be used by the HCW and coughing patient to prevent the spread of infection in the ward, referred to as "source control" (1-4). Masks were not designed to provide respiratory protection (5), as they have consistently lower filtration efficiency than respirators (6-9) and do not seal to the face. A respirator is a device that protects the wearer against inhalation of small and large airborne particles, that is, it protects the wearer from others who are or might be infected (2).

High-income countries have established infection control programs that can be implemented with good resourcing. The guidelines and advice underlying these programs have been produced by high-income countries for their own social, economic, and health environments. Low and middle income countries may not have the ability or finances to adopt generic infection control or pandemic guidelines, equivalent to those originating from high income countries. The practices occurring in low/middle income countries may be driven by a number of factors other than available scientific evidence – such as available resources, Occupational Health and Safety (OHS) legislation, culture, logistics and cost considerations.

Whilst much has been written about available policies issued by the World Health Organization (WHO), and the US Centers for Disease Control and Prevention (CDC), little is known about the consistency in policies from low and middle income countries, and country-specific issues which can drive different needs. In light of ongoing threats from influenza (H1N1, H5N1 and H7N9) and other emerging infections, it is essential to examine

the policies and guidelines of various organizations and countries to examine whether they are evidence based, and whether there are any issues with the recommendations. This study aimed to examine available policies and guidelines around the use of masks and respirators for HCWs, for the prevention of influenza, SARS and TB; and to describe areas of consistency and inconsistency between guidelines, as well as gaps, with reference to the WHO and the CDC guidelines.

METHODS

The guidelines of two large public health organizations, three high-income countries and six low/middle income countries were purposely selected for inclusion in this study. We included guidelines from two major health organizations which are commonly used internationally as a reference, namely the World Health organization (WHO) and the US Centers for Disease Control (CDC). Guidelines from three high income countries (Australia, Canada and UK) and six middle/low income countries (Bangladesh, China, India, Indonesia, Pakistan and Vietnam) were also selected. The main reasons for purposively selecting these guidelines was that the six low/middle income countries account for 47% of the world's population and represent areas where emerging infectious diseases are likely to arise from. Most of these guidelines were publically available or were accessed through known key contacts, and were available in a language which could be readily translated in-house.

We selected guidelines related to influenza, SARS and TB for this review. Given that influenza has the potential to cause both seasonal epidemics and pandemics; it was chosen as the primary infection of interest. TB was selected as an example of a known airborne infectious disease. In contrast to influenza, TB has a long incubation and infection periods. Lastly, SARS was selected as an example of emerging infectious disease, which required a rapid response.

Search strategy

Information relating to mask and respirator use was extrapolated from the following sources: a) general infection control guidelines; b) disease specific infection control guidelines (influenza, SARS and TB); c) personal protective equipment (PPE) guidelines; d) mask/respirator use guidelines and e) position statements. Documents published in the last twelve years in any language were screened with key words for applicability. In the event that two versions of a guideline were found, the most recent version was included. Four strategies were utilized to locate relevant documents. Firstly, websites including the WHO (plus regional offices), CDC, selected country health departments and other relevant websites were screened. Secondly, a key word search was conducted using Google, with 10 results per page set and the first two pages of hits reviewed. The policies and guidelines were also searched in the native languages of the selected countries through advance search settings in Google. The search results were narrowed down by selecting region (e.g. India), site or domain (e.g. gov) and file type (e.g. pdf). Google translator was used to screen the documents in the native languages and then the selected documents were translated by native language speaking colleagues. Policies and guideline documents were also searched for using Medline, Embase, National Guidelines Clearinghouse, and Google Scholar through key words. Lastly, key personal contacts in the selected countries were contacted in regards to the availability of guidelines in the country. Most of the contacts are employed in government organizations or health institutions.

Collection and analysis

Predefined criteria were used to screen the guidelines for their eligibility. Title and summaries were firstly assessed by AAC and then validated by HS and CRM. The following information was extracted from each of the selected guidelines; country/organization, department, publication year, language, title and recommendation on mask respirator use. The terminology used in different countries and guidelines varied, so a classification system was devised (Table 1).

RESULTS

In most of the guidelines reviewed, the rationale for the recommendations around mask and/or respirator use is not discussed and evidence is rarely provided. The WHO, the CDC and most of the countries recommend masks and/or respirators on the basis of the mode of transmission of influenza, SARS and TB. However, various types of masks and respirators are recommended in the guidelines for low and high risk situations. Although most of the guidelines discuss the importance of training and fit testing for respirator use, very few documents provide details on those procedures. Furthermore, most guidelines do not discuss recommendations on how long masks and respirators should be used and whether reuse is recommended. Only a few mentioned that a single mask could be used for 4 hours (10), 8 hours (11), or even for an entire shift (12). Although cloth masks are also commonly used in resource limited settings, the use and reuse of cloth masks is not discussed in any guideline.

A lack of consistency was identified in regards to the nomenclature used in the documents. The WHO frequently uses the term “medical masks” (13), while CDC uses the term “facemask”. Various terms were also used in the country specific guidelines reviewed. For example, Pakistan uses medical masks, surgical masks is used in the UK, Canada, Australia and India documents, procedure masks is used in the Canadian document and finally facemasks is the term used in Vietnam. The description of low and high risk situations also varied among the general and disease specific infection control guidelines (Table 1).

Table 2.1: Terminology used in guidelines reviewed

Terminology	Classification for this study
Mask; surgical mask; medical mask; procedure mask.	Mask
N95; N99; N100; FFP1; FFP2; FFP3; P1; P2; P3; particulate respirator.	Respirator
Low risk situations described in influenza and SARS guidelines: Close contact within one meter of the patient, close contact within 2 meters of the patient; entering infectious patient's room; clinical care; all patient contact; when infected patient used masks; routine care; in screening area; during patient transport; before and after patient contact and risk of splashes into face.	Low risk situations
Low risk situations described in TB guidelines: Low risk facilities including sputum microscopy centers; district and sub district level hospitals.	
High risk situations described in influenza and SARS guidelines: Aerosol generating procedures (AGPs); procedures involving the respiratory tract; laboratory specimen collection from respiratory tract; if patients cough forcefully; if patients do not comply with respiratory hygiene; when patients may not be able to wear mask; mortuary and critical care areas.	
High risk situations described in TB guidelines: Exposure to drug resistant organism; culture/DST and other high risk procedures in laboratory, high risk areas; specialized treatment centers and emergency surgery of infectious cases.	High risk situations

For seasonal influenza, the WHO (14) and the CDC (15) recommends that masks be used in low risk situations and respirators in high risk situations. The recommendations from the UK (16), Australia (17), India (18) and Pakistan (19) are aligned with those from the WHO and the CDC. However Canada (20) and Vietnam (12) have a different policy, which recommends masks in both low and high risk situations for seasonal influenza. Regarding the choice of respirator, the WHO, the CDC and most of the selected countries recommend an N95 or its equivalent (FFP2 or P2) respirator for seasonal influenza. The UK, however, recommends FPP3 respirators.

Though the WHO and the CDC have the same policy for seasonal influenza, they differ in their recommendations for pandemic influenza. During an influenza pandemic, the WHO recommends mask use in low risk situations and respirators in high risk situations (14), whereas, the CDC recommends respirators in both situations (21). The guidelines of the UK (22), Canada (23), Australia (4), China (11), India (18) and Pakistan (19) are aligned with those of the WHO (Table 2). For pandemic influenza, the WHO recommends a range of respirators (e.g. P2, P3, FFP2, FFP3, N95, N99 and N100) and the CDC recommend N95 or higher respirators. Canada and most of the low/middle income countries recommend N95 or its equivalent respirators. The UK recommends only FFP3, while Australia recommends P2 or powered air purifying respirators (PAPRs).

The WHO and the CDC have different policies for HCWs in contact with a patient with SARS. The WHO recommends masks in low risk situations and respirators in high risk situations (14), whereas the CDC recommends that respirators be used in both low and high risk situations (24). The UK (25), Canada (26), Australia (27), Pakistan (28) and Vietnam (29) also recommend that respirators be used by HCWs for protection against SARS. Only China has the same policy as the WHO (10) (Table 2). The CDC and most of the countries prefer N95 or equivalent respirators in low risk situations with SARS patients, while the UK recommends an FFP3.

Table 2.2: Policies and guidelines on masks and respirators use by Health Care Workers (HCWs)

Organization/ country	Seasonal influenza		Pandemic influenza		SARS		TB	
	Low risk	**High risk**	**Low risk**	**High risk**	**Low risk**	**High risk**	**Low risk**	**High risk**
WHO (14, 30)	Masks (Medical masks)	Respirators (N95)	Masks (Medical masks)	Respirators (P2/3, FFP2/3, N95/99/100)	Masks (Medical masks)	Respirators (N95)	Respirators (N95, FFP2)	Respirators (N95, FFP2)
CDC, (15, 21, 24, 31)	Masks (Facemasks)	Respirators (N95) or equivalent respirator (e.g., PAPR, elastomeric)	Respirators (N95)	Respirators (N95 or higher respirators)	Respirators (N95)	Respirators (N95 or higher, elastomeric or PAPR)	Respirators (N95)	Respirators (N95 or preferably PAPR)
UK (16, 22, 25, 34)	Masks (Surgical masks)	Respirators (FFP3)	Masks (Surgical masks)	Respirators (FFP3)	Respirators (FFP3), PAPR use is discouraged	Respirators (FFP3), PAPR use is discouraged	Not recommended	Respirators (FFP3)
Canada (13, 20, 26, 32)	Masks (Surgical or procedure masks)	Masks (Surgical or procedure masks)	Masks	Respirators (N95)	Respirators (N95), PAPR use is discouraged	Respirators (N95), PAPR use is discouraged	Respirators (N95)	Respirators (N95)
Australia (4, 17, 27)	Masks (Surgical masks)	Respirators (P2 or N95)	Masks (Surgical masks)	Respirators (P2 or PAPR)	Respirators (P2 or N95)	Respirators (PAPR)	Respirators (P2, N95)	Respirators (P2, N95)
China (10, 11, 33)	Guidelines not located	Guidelines not located	Masks (Surgical or medical masks)	Respirators	Masks (Medical masks)	Respirators	Respirators (N95)	Respirators (N95)
India (18, 35)	Masks (Surgical masks)	Respirators (N95)	Masks (Surgical masks)	Respirators (N95)	Guidelines not located	Guidelines not located	Not recommended	Respirators (N95 or FFP2)
Indonesia (39)	Guidelines not located	Guidelines not located	Not discussed in pandemic plan	Not discussed in pandemic plan	Guidelines not located	Guidelines not located	Guidelines not located	Guidelines not located
Pakistan (19, 28, 36)	Masks (Medical masks)	Respirators (N95, FFP2)	Masks (Medical masks)	Respirators (N95, FFP2)	Respirator (N95 or P2)	Respirator (N95 or P2)	Not recommended	Respirators (N95 or FFP2)
Bangladesh (37, 40)	Guidelines not located	Guidelines not located	Not discussed in pandemic plan	Not discussed in pandemic plan	Guidelines not located	Guidelines not located	Not recommended	Respirators (N95 or FFP2)
Vietnam (12, 29, 38, 41)	Masks (Facemasks)	Masks (Facemasks)	Appropriate selection between masks and respirators	Appropriate selection between masks and respirators	Respirator (N95)	Respirator (N95)	Not recommended	Respirators (N95)

Respirators are recommended by the WHO (30) and the CDC (31) for protection against TB for HCWs in both low and high risk situations. Canada (32), Australia (17) and China (33) have the same policy as previously outlined. In contrast, respirators are recommended only in certain high risk situations in the UK (34), India (35), Pakistan (36) Bangladesh (37) and Vietnam (38) (Table 2). The WHO and most of the selected countries recommend N95 or equivalent respirators for HCWs during low and high risk exposure to TB bacillus. Though the CDC also recommends N95 respirators in low risk situations, elastomeric respirators or PAPR are preferred during high risk procedures (Table 2).

The seasonal influenza guidelines of China, Indonesia and Bangladesh, the SARS guidelines of India, Indonesia and Bangladesh and the TB guidelines of Indonesia could not be located; and the pandemic guidelines of Indonesia (39) and Bangladesh (40) and Vietnam (41) did not make a clear recommendation on mask and respirator use.

Almost all guidelines emphasized the importance of hand hygiene and strongly recommended that HCWs wash their hands before and after patient contact to prevent the spread of respiratory infections. The role of other PPE was discussed in most of the guidelines. The WHO and the CDC recommended gloves, gown and goggles for seasonal influenza and pandemic influenza in accordance with standard precautions, i.e. while in contact with infectious material or risk of splash on face or body (14-15, 21). However in the case of SARS and other newly emerging infections, both organizations strongly recommend the use of gloves, gown and goggles for all patient contact (14, 24).

DISCUSSION

Considerable variation was observed amongst the policies and guidelines of the selected health organizations and countries in regards to the use of masks and respirators. The WHO and the CDC have similar policies for seasonal influenza and TB; however, they have different recommendations for pandemic influenza and SARS. There is also a vast amount of variation between the various country recommendations for the three diseases. Influenza related policies of the selected countries were generally in line with the WHO,

while SARS related policies were aligned with those from the CDC. The exceptions were the seasonal influenza policies of Canada and Vietnam and the Chinese SARS policy. The previous experience of these three countries with SARS may be a factor influencing the variation in recommendations. TB related policies of high-income countries are in line with the WHO and the CDC, however the policies of the low/middle-income countries are not consistent with either organization.

Various terms were also used in the guidelines reviewed in relation to the products. This indicated that there is no standard terminology or classification for masks. Although the general term “respirator” is constantly used in the guidelines, products with various filtration capacities were recommended for the same diseases. This was especially apparent with regards to the selection of respirators for use during high risk procedures. In some cases, a particular type of respirator recommended by one country was actually discouraged by another country. For example, the CDC and Australia recommend PAPRs for high risk situations during SARS, whereas, Canada and the UK discourage PAPR use due to the risk of self-contamination (25-26). Elastomeric respirators or PAPRs were only recommended for use by the CDC and high income countries.

The availability of resources/funding and more stringent OHS regulations in these high-income settings may be factors influencing this trend. Aside from the variation in terminology previously described, some low and high risk situations were classified in a different way. For example, the CDC and Canada recommend respiratory protection within 2 meters of an influenza case, which is different from the WHO policy (1 meter). OSHA also recommends a 2 meter distance (42). The rationale for 2 meters is not provided in either guideline. Similarly, the Canadian pandemic plan considers it high risk if patients cough forcefully, and/or if patients do not comply with respiratory hygiene (23) and the Australian pandemic plan defines high risk as when an infected patient may not able to use masks (4). However, neither plan provides evidence to support these recommendations.

The WHO and all selected countries have the same policy for pandemic influenza as for seasonal influenza. The WHO policies are flexible and probably take into account the possibility that resource issues could occur. In comparison, the CDC policy is different from the policies of the WHO and other countries. Due to a lack of pre-existing immunity to pandemic influenza strains, and the potential for the occurrence of severe disease and a high mortality, the CDC recommends respirators. The CDC policies are relatively stringent and may be influenced by the US Occupational Health and Safety Administration (OSHA) recommendations. In the US, the OSHA respiratory protection standard regulates the use of respirators in the workplace. Under regulation 29 CFR 1910.134, employers are required to provide respirators to employees for protection from respiratory hazards (43). The OSHA recommends using N95 or higher respirators for HCWs exposed to pandemic influenza (2) and SARS (44).

As highlighted in the results, the use of masks and respirators is not discussed in the pandemic plans of some countries. Our findings corroborate those of the WHO, which conducted a comparative review of pandemic plans and found that only 33/76 (45%) of national plans discuss the role of masks, respirators and other PPE (45). Respiratory protection is most important during the early stages of a pandemic, when the mode of transmission and virulence characteristics are uncertain, and when pharmaceutical measures; such as vaccines and/or antivirals, may not be available or delayed (2, 46). Studies have demonstrated that masks reduce the amount of virus emitted by the wearer and could be a means of source control (47). Therefore, mask use may prevent the spread of infections from HCWs to patients and other people surrounding them.

Uncertainty around the primary mode of transmission of influenza may be another reason contributing to the variations between the recommendations made by each country. Currently the relative contribution and significance of the each transmission mode has not been established (48-50). Most of the information regarding the modes of transmission of influenza is based on old experiments, observational studies during

outbreaks or on other in-direct research, for example drug and vaccine trials (46). Droplet and contact are traditionally thought to be the main modes of transmission for seasonal influenza (2, 22, 51-53). Droplet transmission is via large particles (typically > 5 um) that do not suspend in the air, while airborne transmission occurs through the dissemination of small virus containing particles (typically < 5 um) or droplet nuclei in the air. However some researchers argue that the evidence regarding droplet and contact being the main modes of transmission is not adequate (54) and there is more proof available in favour of the transmission of influenza through the aerosol mode (55-64). Given the ongoing debate about transmission, it is perhaps not surprising that none of the guidelines use evidence around influenza transmission to justify the selection of masks.

Droplet and contact are thought to be primary modes of transmission of SARS (65), yet the use of respirators is highly recommended by the CDC and most of the countries in both low and high risk situations. In comparison, the WHO currently recommends masks for low risk situations and respirators for high risk. Only low levels of evidence may be contributing to this difference. Most of the SARS guidelines are based on retrospective, observational studies conducted during the 2003-04 SARS outbreak. During that period, the WHO recommended that HCWs to use respirators (66). However, the WHO updated its policy in 2007 and stated, “The current evidence suggests that SARS transmission in health care settings occurs mainly by droplet and contact routes. Therefore a medical mask is adequate for routine care”. The CDC, however, maintains its position and continues to recommend a respirator (1). In the CDC guideline, the rationale of the airborne precautions for SARS is discussed in detail. Respirators are recommended due to the potential for airborne transmission, the frequency of aerosol generating procedures (AGPs) and the high case fatality rate among the HCWs. Unlike the WHO, the CDC discussed studies which favour airborne transmission of SARS (67).

There is also a lack of evidence based guidelines in regards to the use of masks/respirators when treating TB patients. The WHO quoted 13 studies on mask and respirator use for TB

patients and concluded that there is little evidence about the effectiveness of respirators (30). However the guideline states that "The available evidence, although weak and indirect, generally favors respirator use for protecting the wearer from TB". High prevalence of TB in low income countries and increased chances of exposure due to respiratory aerosols in the health care facility setting could be an explanation for this recommendation. However, only the recommendations from Canada, Australia and China are aligned with the WHO and the CDC. Most of the low income countries recommended the use of respirators only when undertaking high risk procedures on patients with TB. Interestingly, the selective use of respirators when treating this patient group was also recommended in the UK policy. The UK recommendations have not been amended since 1994 , when the British Thoracic Society (BTS) issued guidelines on the control and prevention of tuberculosis in the UK (68).

Regardless of the mode of disease transmission, all guidelines recommended the use of respirators while performing high risk procedures on influenza, SARS or TB patients. Studies have demonstrated that respiratory aerosols are produced more during AGPs. For example, the risk of influenza and SARS have been shown to increase after tracheal intubation and non-invasive ventilation (69-70) and risk of TB increases after bronchoscopy and sputum induction (71). Therefore respirators are preferred during high risk procedures, as they filter small particles and are designed to provide respiratory protection. Inhaled air passes through the respirator filter and small respiratory aerosols are captured through diffusion and electrostatic mechanisms (72-73).

Training and fit testing are important components of a respiratory protection program and the efficacy of respirator use improves after HCWs are fit tested (74-75). The risk of inhalation of infective particles is reduced if respirators are properly fitted to the face (64). Although the WHO and the CDC discuss the role of fit testing in most of their guidelines, very few countries explain the procedure in detail. Guidelines from low and middle income countries largely ignored this issue. Many of the guidelines reviewed also did not

specify the maximum duration a single mask could be used for, while others varied in the times suggested. Advice pertaining to the reuse and extended of a mask/respirator was also not covered in most of the guidelines.

Even though the use/reuse of cloth masks is common, especially in low resource countries such as China (76) and Vietnam (77-78), none of the guidelines reviewed covered the use of these products. Currently, there are a lack of data to either support or refute the effectiveness of woven cloth masks in blocking influenza or other virus transmission and fluid resistance. Regulatory standards require that surgical masks not permit blood or other potentially infectious fluids to pass through to or reach the wearer's skin, mouth or other mucous membranes under normal conditions and for the duration of time that the protective equipment will be used. As it is not clear that cloth masks or improvised masks can meet the standards set by regulatory bodies and without better testing and more research, cloth masks or improvised masks generally have not been recommended as effective respiratory protection devices, or as devices to prevent exposure to splashes (72). Currently there are no clinical trial data on the efficacy of cloth masks and most of the available studies are in-vitro (79-84). Available evidence suggests that cloth masks may provide some protection, but it is assumed to be considerably less protection than surgical masks and respirators (85). However, it is theorized that some types of cloth fabric may provide better protection (86). In a report by the US National Institute of Health's (NIH) committee on the development of reusable facemasks for use during an influenza pandemic, committee members were hesitant to discourage the use of cloth masks, but suggested caution around their use as they were not likely to be as protective as surgical masks or respirators (72).

This review has some limitations. Firstly, the guidelines from some countries could not be located, while others did not specifically address the use of masks and respirators. Secondly, while we tried to search for the most updated version of guidelines; some countries may have updated the documents and not made them publicly available. Finally,

this study focused on selected high, middle and low income countries, but did not analyse every country. The situation may be different in these countries. For example, France recommends FFP2 and Austria recommends FFP3 respirators for the HCWs in low and high risk situations during pandemics (22). These policies are in line with the CDC policy. On the other hand, policies of the European CDC around the use masks and respirators are the same as those of the WHO (87).

CONCLUSION

Health organizations and countries have different policies and guidelines around mask and respirator use for influenza, SARS and TB. These policies not only vary regarding the choice of product used but also the application and specifications. These differences may reflect the relative lack of level-one evidence available to inform policy development. For the end user in a health care facility setting, the conflicting guidance about mask and respirator use from different sources (such as the WHO and in-country guidelines) may be confusing. Health organizations and countries should jointly evaluate the available evidence and develop a uniform policy on mask and respirator use in the health care setting. The situation in low income settings should be considered and various options should be explored. There is a need to conduct additional studies to generate better evidence to inform policy and current practices. Currently there are major gaps around knowledge about the modes of transmission of respiratory viruses, the efficacy of cloth masks and the impact of extended and re-use of masks/respirators.

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AUTHORS' CONTRIBUTION

AAC, HS and CRM contributed to the design of the study. AAC undertook the search strategy and made the initial selections which were subsequently validated by HS and CRM. AAC developed the first draft of the manuscript and HS and CRM extensively reviewed the paper. All authors read and approved the final manuscript.

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CHAPTER 3: EXAMINING THE POLICIES AND GUIDELINES AROUND THE USE OF MASKS AND RESPIRATORS BY HEALTHCARE WORKERS IN CHINA, PAKISTAN AND VIETNAM

Paper status:

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Declaration

I certify that this publication was a direct result of my research towards this PhD, and that reproduction in this thesis does not breach copyright regulations.

Abrar Ahmad Chughtai (Candidate): 

RATIONALE OF THE STUDY

During the review of policies and guidelines (Chapter 2), I found a lack of discussion in the documents in regard to:

1) Certification, training and fit testing for respirator use
2) Length of facemask and respirator use
3) Re-use of facemasks and respirators, and
4) Use of cloth masks

I conducted a cross sectional survey in three low/middle income countries to elucidate the information collected in chapter 2 and to further examine recommendations around the above mentioned topics.

Research question:

Do health organizations and countries have varying policies and guidelines around the use of facemasks and respirators?

CONTRIBUTION TO THE THESIS

This study upholds the findings of previous study (Chapter 2) and reports inconsistencies in the policy documents. The findings of this study are relevant to low resource settings, where data are limited and resources are scarce. On the basis of results of policy studies (Chapters 2 and 3), three studies were conducted at hospital and staff levels to examine practices around the use of facemasks and respirators (Chapters 4 to 6).

ABSTRACT

Background:

There is an ongoing debate regarding the type of respiratory protection that should be recommended for use for health care workers (HCWs).

Materials and methods:

A cross-sectional survey was conducted in three countries: China, Pakistan and Vietnam.

Results:

In China and Pakistan, the infection control guidelines were developed to be in line with the recommendations from the World Health Organization (WHO) and the US Centers for Disease Control and Prevention, while in the Vietnamese guidelines the recommendations correspond with the WHO guidelines only. The guidelines from all three countries document the need for training and fit testing; however there is no system to monitor training and fit testing programs. Across the three countries, there was some inconsistency with regard to the types of products (i.e. masks vs. respirators) recommended for influenza, severe acute respiratory syndrome (SARS) and tuberculosis (TB).

Conclusions:

Available evidence should be examined and a comprehensive policy should be developed on the use of masks and respirators. The policy should address critical areas such as regulation, training, fit testing and reuse.

INTRODUCTION

Masks and respirators are commonly used in health care settings to protect hospital health care workers (HCWs) from respiratory infections (1, 2). Masks are used to prevent HCWs from acquiring infections from splashes of blood and body fluids and to reduce the transfer of potentially infectious body fluids in a sterile area such as an operating theatre (OT). They are also used by coughing patients to try and prevent the spread of infections (2, 3). However, masks were not designed to provide respiratory protection, as they have consistently lower filtration efficiency than respirators (4, 5). In comparison, a respirator is a device that protects the wearer against the inhalation of small and large airborne particles, that is, it protects the wearer from others who are or might be infected (6). Respirators are generally considered to be superior to surgical or cloth masks (7-9), however there is some evidence that both surgical masks and respirators are effective against respiratory infections (10, 11). The efficacy of both is still being debated in the literature. Although previous observational and experimental studies have reported that masks and respirators may protect HCWs from respiratory infections (7, 8, 12, 13), there is very little high quality clinical evidence to determine their efficacy (14, 15).

A recent review of the policies and guidelines from the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and from three high-income countries and six low/middle income countries highlighted that each organization/country has different approaches and recommendations regarding the use of masks/respirators in the hospital setting (16). The type of product recommended and terminology used to describe the product, were the main inconsistencies observed. In addition, most of the guidelines did not provide any detail about the length of use, reuse and extended use of masks and respirators (16).

To further explore the issues which arose during the guideline review, a cross sectional survey was conducted in China, Pakistan and Vietnam. The aims of this study were to explore the recommendations around mask type recommended in these countries and to

clarify if there are any recommendations regarding use and reuse of various types of masks and respirators.

METHODS

A cross sectional survey was undertaken in three countries: China, Pakistan and Vietnam. Data collection was undertaken between March and September 2013.

Participants

A range of stakeholders from the three countries were identified to participate in the study, including those from the: (1) Ministry and the Department of Health; (2) in-country Center for Disease Control and Prevention; (3) vertical disease control programs; and (4) relevant public and private health organizations involved in the development of infection control policies and guidelines.

We liaised with local researchers from each country, to assist with obtaining local ethics approval, to identify and recruit key stakeholders and to undertake the survey via a face-to-face interview. The local researchers were located in various health departments including the Beijing Center for Disease Control and Prevention (CDC) in China, the National TB Control Program (NTP) in Pakistan and the National Institute of Hygiene and Epidemiology (NIHE) in Vietnam.

An invitation letter was sent to the identified stakeholders in each of the countries via email or mail. The stakeholders were called one week later to confirm whether they had received the letter and whether they were interested in participating in the study. If they agreed, the local researchers conducted a face-to-face interview. If the identified stakeholder was not the relevant person or did not have all information required to answer the questions, he or she was asked to provide the contact details of another suitable person in the organization. Participants were only included in the study when full written consent had been received. Five stakeholders from each country were identified and interviewed.

Survey

A structured questionnaire was developed based on our previously published studies (7, 8) and on the currently available guidelines regarding the use of masks and respirators from each of the countries (16). The questionnaire explored the following aspects: (1) development of the guideline/policy (year of development, authorship etc.); (2) policy and/or recommendations made for the use of masks and respirators for influenza, severe acute respiratory syndrome (SARS) and tuberculosis (TB) (what types of masks and respirators are commonly recommended?; What is the policy around the use of cloth masks?; What are the policies around the regulation, training and fit testing?) and (3) Policies in place for re-use of masks and respirators (Is re-use recommended or not?; What are common decontamination techniques?). Both closed and open ended questions were included in the survey. The questionnaire was pilot tested in one country, and then further refined. The questionnaire was translated into Chinese and Vietnamese languages.

Three diseases were selected for this study: influenza, SARS and TB, based on previous analysis of policies an guidelines (16). The risk of these diseases is assumed to be higher amongst HCWs in comparison to members of the general public, and awareness about policies around these diseases was assumed to be higher (17-19). Influenza was selected as the primary infection of interest and includes seasonal, avian and pandemic influenza. Newly emerging infections have increased in recent years, resulting in morbidity, mortality, and an increase in associated costs. SARS was selected as an example of an emerging infectious disease. TB was selected as an example of an airborne infectious disease. In contrast to influenza and SARS, TB has a long incubation and infectious periods.

Mask and respirator reuse are referred to in this study as extended use and re-use after decontamination. Extended use was defined as mask or respirator use by the same wearer for a long time i.e. for more than one shift or day. Re-use after decontamination was defined as decontaminating masks or respirators and reuse by same or a different wearer.

Data collection and analysis

Local research groups completed the survey via a structured interview. The survey was completed in the local languages in China and Vietnam and in English in Pakistan. All interviews were audio recorded and transcribed. The research groups in China and Vietnam transcribed the surveys into English before the analysis stage. Survey data were entered into an Excel Spreadsheet 2010 (Microsoft Corporation). Separate tables were made for each country and question type. Open ended questions were examined and coded for themes and subthemes and thematic analysis was performed. Two researchers (AAC and HS) reviewed all data and prepared a list of themes and subthemes separately. Both lists were then collectively reviewed and a final list of themes and subthemes was prepared, and applied to whole dataset. Data were double checked for errors. In case of gross errors or inconsistencies, the original recordings were referred to.

Ethics approval

Primary ethics approval was obtained from the Human Research Ethics Advisory (HREA) Panel of the University of New South Wales, Sydney Australia (Approval no 2012-7-40). Approval was also sought from Beijing Center for Disease Control and Prevention (CDC) China, Pakistan Medical and Research Council (PMRC), Islamabad Pakistan and the Institutional Review Board at the National Institute for Hygiene and Epidemiology (NIHE), Hanoi Vietnam.

RESULTS

In all of the surveyed countries, recommendations regarding the use of masks/respirators were captured in both general infection control policies, as well as disease specific guidelines for seasonal influenza, pandemic influenza, avian influenza, SARS and TB. The majority of the documents are targeted at health care providers; however some also include recommendations for patients and community members. Although the guidelines from both Pakistan and China discuss in detail the use of masks/respirators, only the

Chinese policy includes information regarding the regulation and certification processes for respirators. In Vietnam, the use of masks/respirators is only briefly discussed in the national policy. While the guidelines from all three countries document the need for training and fit testing, there is no specific guidance provided about the implementation and monitoring of training/fit testing programs.

Guidelines on the use of personal protective equipment (PPE) used when dealing with respiratory viruses of unknown origin partially existed in China and Vietnam prior to the 2002-03 SARS outbreak. According to the participants interviewed, most of these guidelines were developed during the SARS outbreak. The quality and effective use of masks were emphasized in the new guidelines. During the 2009 H1N1/A influenza pandemic, participants from all three countries reported that further revisions were made to the guidelines based on information obtained from the WHO and the CDC. In the initial phase of the pandemic, N95 respirators were recommended for everyone; however, this recommendation was subsequently revised later on so that N95 were only recommended during high-risk procedures.

In light of the recent emergence of a novel coronavirus (MERS) and influenza H7N9, new infection control guidelines are currently being developed in China. Pakistan is also developing a guideline on TB infection control in health care facilities and updating the policy on hand hygiene.

With regards to the use of PPE for HCWs, the recommendations from Pakistan and China were developed to be in-line with the recommendations made by the WHO and the CDC. During the initial development stages, the European Center for Disease Control (ECDC) guidelines were also considered. In comparison, only the Vietnamese guidelines are in line with those of the WHO.

When asked to clarify whether specific recommendations for mask use were made according to a risk classification, participants from all three countries confirmed that they were. The description of low and high-risk situations, however, varies in the guidelines

(Table 1). Across the three countries, there is some inconsistency about the types of products recommended for seasonal influenza, pandemic influenza, avian influenza, SARS and TB. For seasonal, and pandemic influenza; paper, cloth and surgical masks are all recommended for low risk activities, whereas, only surgical masks and respirators are recommended in high risk activities. For dealing with either a SARS or an avian influenza patient, the guidelines vary between country and between high/low risk situations. Various mask types are recommended for use in low risk clinical situations with a TB patient, whereas surgical masks and respirators are recommended in high risk situations. Paper and cloth masks are less commonly recommended in China and Pakistan, than in Vietnam.

"Extended use" of masks is not recommended in the Chinese and Vietnamese guidelines; however, during the interviews in Pakistan it was suggested that the practice is commonplace. In comparison, the "reuse" of masks and respirators is not recommended in any guidelines. According to the Vietnamese guidelines, reuse of wet masks is not recommended, nor is it recommended to place a mask into a pocket or wear it loose around the front of neck for the purpose of reuse. However, when reflecting about the reuse of masks, participants highlighted that the recommendation of only using a mask once was infeasible because of cost and that in reality staff often resort to reusing their masks or extending the time they are worn for.

Table 3.1: Description of low and high-risk situations in various infection control policies and guidelines in China, Pakistan and Vietnam

Country	Description of low risk	Description of High risk
China	• Splashes of blood or other body fluids	• Endotracheal intubation • On some special circumstances
Pakistan	• Splashes, body fluids, secretions and droplet infections • Attending patients in OPD clinic • Low risk pathogens	• Highly communicable diseases of airborne route e.g. TB, viral haemorrhagic fever, plaque or SARS • High risk-dealing with patients suffering from viral haemorrhagic fever, bird flu etc. • High risk pathogens
Vietnam	• Bacterial infection • No contact with infectious diseases transmitted by respiratory route HCWs who work in examination department and wear surgical masks • Normal patients or patients without respiratory infections	• Working in laboratory with SARS, avian influenza, pandemic influenza and seasonal influenza without full immunization • Places of care for patients with SARS, pandemic influenza • High risks were classified by levels, for instance o HCWs who have contact with influenza, TB patients o HCWs dealing with influenza A or respiratory diseases

Participants discussed various challenges regarding the implementation of national policies and guidelines. Despite the development of guidance documents, participants felt that the guidelines are rarely followed, which may be due to a number of reasons including a lack of regulatory mechanisms, scarce resources and unavailability of trained staff. It was also suggested that the implementation of guidelines also varies among public and private hospitals. Most hospitals do not have established infection control committees, nor do they have arranged training programs for staff. Some participants proposed to establish national groups for monitoring guideline implementation. Other

participants suggested that health departments should lead the process and provide updated information on use masks and respirators in health care setting.

DISCUSSION

In this study we explored the recommendations around the use of masks and respirators from three Asian countries. In all of the settings, national infection control policies and disease specific policies for pandemic influenza, seasonal influenza, avian influenza, SARS and TB are in existence; however the recommendations regarding the types of masks that should be used differ. Most of the guidelines were developed in the aftermath of either the SARS outbreak in 2002-03 or the emergence of avian influenza in 2004-2005.

The results from this study highlight the variations across the three countries in regards to the recommendations and guidelines around the use of masks/respirators. In low risk situations, various products are being recommended by all three countries, ranging from paper masks, cloth masks, surgical masks and respirators. However in high-risk situations, surgical masks and respirators are commonly recommended in all three countries.

Currently it is not apparent what factors are being taken into account when these recommendations are being made. In an ideal setting, the selection of an appropriate type of respiratory protection should depend on the mode of disease transmission. Droplet and contact are considered the primary modes of transmission for influenza (20, 21) and SARS (22), therefore surgical masks may be sufficient to protect HCWs during routine care. However studies have shown that the risk from infections increases during 'high risk situations', for example when undertaking tracheal intubation, bronchoscopy, non-invasive ventilation and other aerosol generating procedures (AGPs) (23-25). The risk is primarily due to increased production of respiratory aerosols during these procedures, which might contain more virus (26). In addition some diseases, like TB, exclusively transmit through respiratory aerosols (2, 27). Respirators should be preferred when there is risk of aerosol transmission as they are designed for respiratory protection and are more effective than surgical and cloth masks (7-9).

As highlighted by our participants, the development of national guidelines was in accordance with either the recommendations from the WHO or from the US CDC or both. As previously documented by our team, the WHO and the CDC themselves differ in their recommendations regarding the use of masks/respirators for some diseases (16). This probably explains some of the differences identified in this present study. However it does not explain all of the choices being made. For example, paper and cloth masks are not recommended by the WHO or the CDC but were listed in the policies from all three countries. Although the efficacy of cloth masks is not proven yet and their role in prevention of infections is uncertain (28), cloth masks may be the only option available to HCWs in some situations due to resource and financial limitations. For example, cloth masks were commonly used in China (29) and Vietnam (30) during the SARS outbreak in 2002-03. There is a clear gap in cloth mask research and very few studies have been conducted to test the efficacy of cloth masks since the development of surgical masks in middle of the 20th century (31). There is a need to conduct further research on cloth masks that focuses on improving the design and material, given that some countries will continue to depend on them. In our study, only China has regulations on the use of respirators. Although respirators are being used in the Pakistan and Vietnam, there is no regulatory body to monitor their use. In some hospitals in Vietnam, the Department of Hospital Infection Control monitors the use of masks, hand hygiene and sterilization; however there is no central regulatory body. Regulations over the use of respirators exist in most high income countries. For example, the National Institute for Occupational Safety and Health (NIOSH) regulates the testing and certification of respiratory protection equipment in the US. The NIOSH tests filters for the effects of loading, particle burden, temperature, and relative humidity and requires a minimum filtration efficiency of 95%, 99% or 100% (3). In Europe, the European Norm (EN) standards are followed for testing respirators. The respirators are required to be marked with 'Conformité Européen' (CE), which means that, the respirator meets the criteria of the EN certification(32). In Australia, the AS/ NZS 1716 standard regulates respirator use (33). In low/middle income

countries, barriers such as lack of resources, government motivation and technical expertise may impact the introduction of similar regulations.

In our study, extended use was recommended only in Pakistan while the reuse of masks was not recommended in any country. Currently there is a lack of information regarding the period in which the same mask or respirator may be used continuously. Generally, disposable masks and respirators have a limited life span and may become deformed, damaged or infective after single use (28). Re-use after decontamination is defined as decontaminated masks or respirators reused by same or different wearer. Decontamination of masks and filtering piece respirators is usually not feasible because the materials of these masks are likely to degrade with standard means of disinfection, for example boiling, chemicals, heat and radiation (28). Currently there is no standard method to disinfect disposable masks and respirators. Ultraviolet germicidal irradiation (UVGI), microwave-generated steam (MGS), moist heat (MH), ethylene oxide and vaporized hydrogen peroxide are a few options, which have been previously suggested to decontaminate respirators (34, 35).

The reuse of masks and respirators is generally not recommended due to risk of self-contamination and adverse events(28), however, this may be the only option in some resource limited settings or during outbreaks and pandemics. During the SARS outbreak, Health Canada advised hospital staff to use their masks and respirators for an extended period if their patient was SARS negative (36). The WHO advises HCWs to use respirators for extended periods for TB protection, if they are properly stored (37).The CDC recommends that extended use and re-use should be balanced against the risk of infection and extended use is preferred over re-use if required (38). Further studies should be conducted to examine the effectiveness of masks being used for extended periods and to test the effectiveness of various decontamination methods. The number of virus particles isolated, length of virus survival, effect on mask material and HCW compliance are important factors to consider when recommending mask re-use (28, 38).

Our study has some limitations. While we attempted to identify the most relevant participants from various health departments and organizations, we may have failed to include all relevant stakeholders. However, given that we worked with local health organizations to recruit participants, we feel that this limitation was minimized. In addition, there was a chance of recall bias due to the time of guideline development. A few of the guidelines were developed before 2003 and participants may not have been able to recall some of the recommendations. These newer guidance documents may contain more up to date recommendations, which are not included in this study.

CONCLUSION

Countries have various policies and guidelines around the use of masks and respirators. Paper, cloth and surgical masks are generally recommended for low risk situations, whereas for high-risk situations, surgical masks and N95 respirators are suggested. There are many gaps in the guidelines and extended use and re-use are not discussed in most of the guidelines. There is a need to examine available evidence and develop a comprehensive policy on the use of masks and respirators in various respiratory infections. The policy should address critical areas, like regulation, training and fit testing. A mechanism should be developed to monitor the process of guideline implementation.

DECLARATION OF CONFLICTING INTERESTS

Professor C. Raina MacIntyre: Raina MacIntyre has held an Australian Research Council Linkage Grant with 3M as the industry partner, for investigator driven research. 3M have also contributed supplies of masks and respirators for investigator-driven clinical trials. She has received research grants and laboratory testing as in-kind support from Pfizer, GSK and Bio-CSL for investigator-driven research. Dr Holly Seale had a NHMRC Australian based Public Health Training Fellowship at the time of the study (1012631). She has also received funding from vaccine manufacturers GSK, bio-CSL and Sanofi Pasteur for investigator-driven research and presentations. The remaining authors declare that they have no competing interests and have no nonfinancial interests that may be relevant to the submitted work.

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CHAPTER 4: PRACTICES AROUND THE USE OF FACEMASKS AND RESPIRATORS AMONGST HOSPITAL HEALTHCARE WORKERS (HCWS) IN THREE DIVERSE POPULATIONS

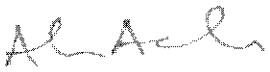
Paper status:

The following paper constitutes chapter 4 of the thesis and has been accepted for publication in American journal of infection control in form of a short report.

Chughtai AA, MacIntyre CR, Ashraf MO, Zheng Y, Yang P, Wang Q, Dung TC, Hien NT & Seale H (2014). Practices around the use of facemasks and respirators amongst hospital healthcare workers (HCWs) in three diverse populations. 2015. American journal of infection control (In press).

Declaration

I certify that this publication was a direct result of my research towards this PhD, and that reproduction in this thesis does not breach copyright regulations.

Abrar Ahmad Chughtai (Candidate): 

RATIONALE OF THE STUDY

While health agencies and governments may recommend certain practices (Chapters 2 & 3), in reality what occurs in the hospital setting may be very different. It is therefore important to examine the translation of policy into practice at the hospital and staff levels. I conducted a cross sectional survey in three low/middle income countries to see whether national infection control policies and guidelines for use of facemasks/respirators are being complied with in the hospitals or not.

Research questions:

(1) Do hospitals follow national infection control policies and guidelines for the use and re-use of facemasks?
(2) What types of facemasks are being used at the hospital level?

CONTRIBUTION TO THE THESIS

This study reflects on the practices regarding the use of facemasks and respirators in the hospital setting, such as type of product used by HCWs, duration of use and extended use/re-use after decontamination. The results show that policies are not translated into clinical practice and various types of facemasks and respirators are being used by HCWs in the hospitals. Moreover, non-standardised practices are common in low resource countries such as extended use and re-use of facemasks and respirators and the use of cloth masks. As various types of products are recommended in the policy documents, I also compared quality and filtration efficacy between the facemasks/respirators being routinely used in selected hospitals. The findings of this study are important for the development of recommendations around the use of facemasks and respirators in low resource settings.

Background:

This study aimed to examine the clinical practices occurring in hospital wards around the use of facemasks and respirators.

Methods:

A cross sectional survey was conducted in 89 secondary/tertiary level hospitals located in Punjab, Pakistan (n=55), Hanoi, Vietnam (n=15) and Beijing, China (n=19). Samples of facemasks and respirators commonly used in the hospitals were collected and examined.

Results:

Various types of facemasks (medical, cloth and paper masks) and respirators are being used by healthcare workers (HCWs) in the three countries. Medical masks and respirators are generally used in Beijing; medical masks in Punjab; and a range of products in Hanoi; ranging from paper and/or cloth masks, to medical masks and respirators. Very few hospitals reported that HCWs undergo a medical evaluation, training and/or fit test prior to respirator use. Extended use and re-use of facemasks are common practices. A review of the samples revealed large variations in the products being used in terms of shape, layers and filtration efficiency.

Conclusion:

Varied practices around the use of facemasks are probably influenced by the available resources and local recommendations. Non-standardised practices are common in low resource settings, which may be placing HCWs at risk. There is a need for research on the extended use and re-use of facemasks, as well as a need to develop an evidence based, comprehensive and uniform policy on facemask use.

INTRODUCTION

The debate around what is considered appropriate respiratory protection has been renewed since the recent emergence of new pathogens such as influenza A(H1N1)pdm09 virus, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), avian influenza A(H7N9) and Ebola virus disease (EVD) (1-5). Health care workers (HCWs) are at the frontline when it comes to dealing with newly emerging or re-emerging pathogens and are at increased risk of contracting infections compared to the general public (1, 6-8). In addition, HCWs can also be a source of infections and can spread these pathogens to patients and other people around them. Various types of respiratory protection devices are being used by HCWs around the world, ranging from medical masks, cloth masks, paper masks (all types of masks hereinafter referred to as "facemasks") and respirators. In the health care setting, facemasks are used to protect wearers from splashes and sprays of blood and body fluids and to prevent spread of respiratory infections to others, while respirators are used for respiratory protection of the wearer (9-11).

Recently we reviewed the guidelines around the use of facemasks/respirators and found that various health organisations and countries have adopted different approaches and recommendations regarding the use of facemasks/respirators in the hospital setting (5, 12). We also identified that the type of product recommended and terminology used to describe the product, were also inconsistent across the guidelines reviewed. Most of the guidelines did not discuss policies on re-use and extended use of facemasks. (5). Although policy documents recommend staff training and fit testing prior to using a respirator, countries may not have systems to monitor these programs (12).

Currently no published data are available from health organizations in low and middle income countries (hereinafter referred to as "low resource countries") in regards to their practices around the use and re-use of facemasks and respirators. While health agencies and governments may recommend certain practices, in reality behaviours occurring in individual organisations may be very different and are probably influenced by various factors including staff understanding of disease transmission modes, occupational health

and safety obligations, staff knowledge and attitudes towards the infections, availability of products and other individual, organisational and environmental factors. This study aimed to examine the authentic practices that occur in hospital wards regarding the use of facemasks. In addition, we compared whether there is any variation in the quality and filtration efficacy between the facemasks/respirators being routinely used.

METHODS

A cross sectional survey was conducted amongst district and tertiary care level hospitals in Beijing, China (2 districts), Punjab, Pakistan (36 districts) and Hanoi, Vietnam (14 districts). A convenience sample of hospitals was purposefully selected in collaboration with local researchers from each country. Invitation letters and participant information sheets were sent to the hospital administrator(s) and/or infection control coordinator of each of the selected hospitals. Consent was implied if they completed and returned the questionnaire.

Three diseases were selected for this study: influenza, severe acute respiratory syndrome (SARS) and tuberculosis (TB) (5). The risk of these diseases is assumed to be higher amongst HCWs in comparison to the members of general public (1, 6-8). Influenza (including seasonal, avian and pandemic) was selected as the primary infection of interest. Given the recent emergence of MERS-CoV, we felt that it was also important to examine the practices at each of the hospitals with regard to dealing with emerging infections. We used SARS as an example of an emerging infectious disease. Lastly, TB was selected as an example of an airborne infectious disease. In contrast to influenza and SARS, TB has long incubation and infection periods.

Data collection

A questionnaire was developed by the research team and was based on our published studies (13, 14), a review of policies and guidelines on the use of facemasks and respirators (5) and our previous health department survey (12). The questionnaire aimed to examine the following key areas: (a) infection control policies and guidelines followed in the hospital; (b) practices regarding facemask and respirator use/re-use by HCWs for

each disease of interest; and (c) the use of facemasks and respirators in outbreak and other high demand situations. Closed and open-ended questions were included in the questionnaire. Documents were translated into the local language in Vietnam and China, while the survey was administered in English in Pakistan. Prior to commencing the study, the questionnaire was piloted in one country.

In this study, cloth/cotton/gauze/fabric masks were categorised as “cloth masks” and medical/ surgical/dental/procedure masks were categorised as “medical mask”. “Paper masks” (a type of facemasks with single layer) were categorised separately. Previous studies and policy documents showed that paper masks are commonly used in low resource countries (15-18). N95/N99/N100/P2/P3/FFP2/FFP3 respirators were categorised as “respirator”. The respirators tested and labelled by a regulatory body such as the US National Institute for Occupational Safety and Health (NIOSH) (19), were categorised as “certified respirators”. We defined ‘extended use’ as ‘a facemask or respirator being used by the same wearer for a long time i.e. more than one shift or day’ and defined ‘reuse’ as ‘decontaminating the facemask or respirator for reuse by the same or different wearer’.

Testing of facemasks and respirators

Hospital administrators/infection control coordinators were also asked to send samples of facemasks and respirators being worn in the hospital. Participants were asked to collect facemasks/respirators from wards/departments where patients with potential respiratory diseases are treated. Only new (clean) facemasks and respirators were collected and examined for: design (flat, cup or duckbill shape), size (length and width), material manufactured from, number of layers and folds and type of attachment design (head loop, ear loop or strings).

Following the gross examination, 25 different models of facemasks/respirators were identified as being used across the three countries: N95 respirators (n=10), medical mask (n=9), and cloth masks (n=6). The particle filtration efficiency (PFE) of these samples was

tested to find out if there was any difference in performance of the products and to examine how they compared with each other. The TSI 8110 Filter Tester was used to test the filtration performance of the facemasks and respirators in accordance with respiratory standard AS/NZS1716 (20). In summary, the filter is challenged by a known concentration of sodium chloride particles, within the size range 0.02 to 2 µm equivalent diameter and a mass median particle diameter of approximately 0.3 to 0.6 µm. The flow rate used was 95 L/min. The particle concentration is measured before and after the filter material and the relative filtration efficiency calculated.

Hospital administrators/infection control coordinators were asked to send questionnaires and samples of facemasks and respirators to the local research team, who was then responsible for translating the questionnaire into English.

Analysis

Questionnaire data were entered into an Excel spreadsheet (Microsoft Corporation) and separate tables were made for each country and question type. Data were double checked for errors and in case of gross errors or inconsistencies, the original recordings were referred to. The data of facemask/respirators was entered in the SPSS software version 21.0 (IBM Corp. New York. 2011). Content analysis was done for the open-ended questions using NVivo 10 software (QSR). A preliminary list of themes and sub-themes was prepared by AAC and HC on a subset of data and then agreed thematic framework was applied to other data.

Ethics approval

Primary ethics approval was obtained from the Human Research Ethics Advisory (HREA) Panel of the University of New South Wales, Sydney Australia (2013-7-02). Approval was also obtained from Beijing Center for Disease Control and Prevention China, Pakistan Medical and Research Council (NBC-120) and the Institutional Review Board at the National Institute for Hygiene and Epidemiology Vietnam (12-IRB).

RESULTS

A total of 89 hospitals agreed to participate in the survey (Beijing: 19; Punjab: 55; Hanoi: 15). These hospitals represent 77% of the total district/tertiary care level hospitals from the selected areas. National infection control guidelines are available in all hospitals in Hanoi, 78.9% (15/19) hospitals in Beijing and 85.5% (47/55) hospitals in Punjab. In addition, most of the hospitals in Beijing also follow disease specific guidelines for seasonal influenza (73.7%), pandemic influenza (73.7%), avian influenza (89.5%), SARS (84.2%) and TB (84.2%). Around two thirds of the hospitals in Hanoi have disease specific infection control guidelines for pandemic influenza (60%) and around one third have guidelines on seasonal influenza (33.3%), avian influenza (33.3%), SARS (33.3%) and TB (40%). In comparison, none of the surveyed hospitals in Punjab reported having disease specific guidelines for influenza or emerging pathogens, while only ten hospitals (18.2%) reported having a TB infection control guideline (Table 1).

Table 4.1: Availability of infection control (IC) guidelines in the selected hospitals in three countries

Infection control policies and guidelines	Beijing (n=19)	%	Punjab (n=55)	%	Hanoi (n=15)	%
National IC policy (general)	15	78.9	47	85.5	15	100.0
Seasonal influenza policy	14	73.7	0	0.0	5	33.3
Pandemic influenza policy	14	73.7	1	1.8	9	60.0
Avian influenza policy	17	89.5	0	0.0	5	33.3
SARS policy	16	84.2	0	0.0	5	33.3
TB policy	16	84.2	10	18.2	6	40.0
Do not know	2	10.5	4	7.3	2	13.3
Do not have any in hospital	1	5.3	0	0.0	0	0.0

**n=number of hospitals*

Type of facemasks/respirators used

The surveyed hospitals in Beijing reported that HCWs mostly use medical masks or respirators to protect from influenza and TB. Medical masks are generally used in low risk situations and respirators in high risk situations. Medical masks were reported to be the most common type used in Punjab to protect from influenza and TB, and are used mainly in high risk situations. Different types of facemasks are used in Hanoi for influenza and TB; ranging from paper and/or cloth masks, to medical masks and respirators (Table 2). Medical masks and/or respirators are generally used by the doctors, nurses and paramedics in Beijing, whereas medical masks are the most common type used in Punjab. In Hanoi, participants reported that doctors, nurses and paramedics mostly use either paper or medical masks. Facemasks are not frequently used by administrative and other support staff in three countries (Table 3).

Table 4.2: Types of facemask/respirator used for influenza and TB in selected hospitals in three countries*

	Seasonal influenza		Pandemic influenza		Avian influenza		Tuberculosis	
	Low risk	High risk	Low risk	High risk	Low risk	High risk	Low risk	High risk
Beijing (19 hospitals)								
Paper mask	1	4	2	5	6	5	1	5
	5.3%	21.1%	10.5%	26.3%	31.6%	26.3%	5.3%	26.3%
Cloth mask	5	4	2	4	7	4	2	3
	26.3%	21.1%	10.5%	21.1%	36.8%	21.1%	10.5%	15.8%
Medical mask	15	6	12	5	0	5	9	5
	78.9%	31.6%	63.2%	26.3%	0.0%	26.3%	47.4%	26.3%
Respirator	3	7	3	15	0	18	8	12
	15.8%	36.8%	15.8%	78.9%	0.0%	94.7%	42.1%	63.2%
Punjab (55 hospitals)								
Paper mask	0	1	0	1	0	1	1	2
	0.0%	1.8%	0.0%	1.8%	0.0%	1.8%	1.8%	3.6%
Cloth mask	5	4	1	3	2	1	8	2
	9.1%	7.3%	1.8%	5.5%	3.6%	1.8%	14.5%	3.6%
Medical mask	6	38	5	12	5	10	8	48
	10.9%	69.1%	9.1%	21.8%	9.1%	18.2%	14.5%	87.3%
Respirator	0	1	0	0	0	0	0	1
	0.0%	1.8%	0.0%	0.0%	0.0%	0.0%	0.0%	1.8%
Hanoi (15 hospitals)								
Paper mask	11	1	6	5	7	4	7	3
	73.3%	6.7%	40.0%	33.3%	46.7%	26.7%	46.7%	20.0%
Cloth mask	9	2	5	3	4	4	4	3
	60.0%	13.3%	33.3%	20.0%	26.7%	26.7%	26.7%	20.0%
Medical mask	9	5	4	7	5	6	5	7
	60.0%	33.3%	26.7%	46.7%	33.3%	40.0%	33.3%	46.7%
Respirator	8	4	8	4	8	4	8	4
	53.3%	26.7%	53.3%	26.7%	53.3%	26.7%	53.3%	26.7%

**The total is more than 100% as most hospitals used more than one types of facemasks*

Table 4.3: Facemasks used by the type of HCWs for influenza and TB in selected hospitals in three countries*

	Paper masks		Cloth masks		Medical masks		Respirators		Not used	
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
Beijing (19 hospitals)										
Doctors	4	21.1	10	52.6	18	94.7	17	89.5	0	0.0
Nurses	4	21.1	10	52.6	18	94.7	17	89.5	0	0.0
Paramedics	4	21.1	7	36.8	16	84.2	12	63.2	0	0.0
Admin	1	5.3	3	15.8	6	31.6	1	5.3	7	36.8
Other	4	21.1	1	5.3	4	21.1	1	5.3	9	47.4
Punjab (55 hospitals)										
Doctors	3	5.5	3	5.5	47	85.5	0	0.0	4	7.3
Nurses	2	3.6	3	5.5	48	87.3	0	0.0	4	7.3
Paramedics	5	9.1	9	16.4	38	69.1	0	0.0	3	5.5
Admin	3	5.5	2	3.6	18	32.7	0	0.0	29	52.7
Other	10	18.2	6	10.9	12	21.8	1	1.8	24	43.6
Hanoi (15 hospitals)										
Doctors	11	73.3	3	20.0	14	93.3	7	46.7	0	0.0
Nurses	11	73.3	3	20.0	12	80.0	6	40.0	0	0.0
Paramedics	6	40.0	3	20.0	6	40.0	2	13.3	0	0.0
Admin	1	6.7	0	0.0	2	13.3	0	0.0	12	80.0
Other	3	20.0	2	13.3	2	13.3	0	0.0	8	53.3

**The total is more than 100% as most hospitals used more than one types of facemasks/respirators*

Respirators are mainly used in respiratory wards, emergency and fever clinics in Beijing, and in respiratory wards in Hanoi and TB wards in Punjab. Certified respirators are used in 11 (73%) Vietnamese hospitals but only in five (9%) hospitals in Punjab. Seven (37%) Beijing hospitals reported using certified respirators, four (21%) did not use them and remaining eight (42%) did not know the answer. Not all sites reported providing training (14/19 in Beijing, 3/55 in Punjab and 13/15 in Hanoi) and/or fit testing (4/19 in Beijing, 3/55 in Punjab and 8/15 in Hanoi) to staff members around respirator use. Medical evaluation for HCWs was reported to occur in only 10 hospitals (11%) from the three countries, 48 (54%) hospitals did not perform it and remaining 31 (35%) did not know the answer.

Length of time facemasks/respirators are used

Hospitals reported that facemasks/respirators are used for varying lengths of time. Paper masks are generally used for 2-4 hours in Chinese hospitals, but less than one hour in most of the hospitals in Punjab. Most hospitals in Hanoi use paper masks for more than one hour, while some even use them for up to a day. Most hospitals in Beijing and Hanoi use cloth masks for more than 4 hours while cloth masks are used for four or less hours in most hospitals in Punjab. Medical masks are mostly used for 2-4 hours in Chinese hospitals, 4-6 hours in Punjabi hospitals and different length of time in Vietnamese hospitals (range from 1 hour up to 2 days). N95 respirators are generally used for 4-8 hours in the selected countries, though most hospitals do not use them or use them only in high risk situations.

Re-use of facemasks/respirators

Re-use of facemasks/respirators following decontamination was reported in 7 (37%) hospitals in Beijing and 10 (67%) in Hanoi. The re-use of facemasks is not a common practice in Punjab, with only three hospitals (5%) reporting the practice. Soap and water was the commonest technique used in Chinese and Vietnamese hospitals to decontaminate masks, while boiling the mask was reported in Punjab. Other decontamination techniques reported included the use of bleach and chemicals.

Purchasing of facemasks/respirators is mostly undertaken by the hospital administration in the three countries. In the last year, 40% hospitals in Hanoi faced shortages of facemasks, compared to only 11% in Beijing and Punjab. Participants reported that it's not uncommon for staff to purchase their own facemasks during periods of shortages. In addition, hospitals give priority to staff in high risk areas such as those who have frequent contact with patients in the exam rooms of the infectious disease department.

Particle filtration efficacy of facemasks/respirators

We collected 369 samples of facemasks/respirators from the three countries: 72 (20%) from Beijing, 75 (20%) from Hanoi and 222 (60%) from Punjab (Table 4). Among the samples collected from Beijing, 58.3% were medical masks, 29.2% were N95 respirators and 12.5% were cloth masks. Samples of medical masks (96.4%) were mostly collected from Punjab hospitals. Among total samples collected from Hanoi, 73.3% were medical masks, 21.3% were cloth masks and remaining 1.4% were N95 respirators. Samples of paper masks were not provided by any hospital. The products are of various sizes, layers (two layers, three layers) and shape (flat fold and cup shape). Most cloth masks collected from Beijing were of three layers, while two layer and one-layer cloth masks are used in Hanoi and Punjab, respectively. Three layer medical masks were collected from Beijing and Hanoi; while around 40% of medical masks used in Punjab were of two layers. All respirators contained three or more layers.

Laboratory tests demonstrated varying filtration efficacy of facemasks/respirators collected from three countries (Table 4). Overall penetration of particles through cloth masks (median 85.5%, range 80-92%) and medical masks (median 53%, range 0.4-93%) was very high compared to the N95 respirators (median 0.6%, range 0.1-30%). The penetration of particles was low with the certified respirators (median 0.3%, range 0.1-0.7%) and higher for the non-certified respirators (median 3%, range 0.1-30%).

Table 4.4: Examination of samples of facemasks/respirators collected from selected hospitals in three countries

Mask type	# of samples collected	Number of layers			Shape		Penetration (median/range %)
		One	Two	Three	Flat	Cup	
Beijing (19 hospitals)							
Cloth mask	9 (12.5%)	0 (0%)	2 (22.2%)	7 (77.8%)	5 (55.6%)	4 (44.4%)	85% (80% to 90%)
Medical mask	42 (58.3%)	0 (0%)	0 (0%)	42 (100%)	42 (100%)	0 (0%)	7% (0.4 to 87%)
Respirator	21 (29.2%)	0 (0%)	0 (0%)	21 (100%)	0 (0%)	21 (100%)	1.5% (0.1% to 30%)
Punjab (55 hospitals)							
Cloth mask	6 (2.7%)	6 (100%)	0 (0%)	0 (0%)	6 (100%)	0 (0%)	66% (85% to 92%)
Medical mask	214 (96.4%)	0 (0%)	87 (40.7%)	127 (59.3%)	214 (100%)	0 (0%)	87% (8.3 to 90%)
Respirator	2 (0.9%)	0 (0%)	0	2 (100%)	0 (0%)	2 (100%)	0.1% (0.1% to 0.1%)
Hanoi (15 hospitals)							
Cloth mask	16 (21.3%)	0 (0%)	15 (93.8%)	1 (6.2%)	14 (87.5%)	2 (12.5%)	66% (85% to 86%)
Medical mask	58 (77.3%)	0 (0%)	6 (10.3%)	52 (89.7%)	58 (100%)	0 (0%)	37% (53 to 93%)
Respirator	1 (1.4%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	1 (100%)	0.3% (0.3% to 0.3%)

DISCUSSION

Through the use of a survey, we identified that various practices currently exist around the use and re-use of facemasks and respirators in low resource settings. Practices not only vary between the three countries examined but also vary within different districts in the countries. The data suggest that hospitals generally do not follow national policies and guidelines regarding the types of facemasks and respirators that should be used. For example, the Chinese Center for Disease Control and Prevention recommends the use of

respirators for TB in both low risk (e.g. while carrying out routine care, and drug sensitive TB) and high risk (e.g. patients with drug resistant TB) situations (21). However, amongst the Beijing hospitals surveyed, it was reported that medical masks are most commonly used when providing patient care to someone with TB in low risk situations and some even use them in high risk situations. Similarly, respirators are recommended in Punjab in high risk situations for both influenza and TB (22, 23), however currently in most hospitals, only medical mask is used to protect staff from these infections. Different types of respiratory protection devices (including paper/cloth/medical masks and respirators) are being used in the hospitals in Hanoi for influenza and TB patients, whereas only medical masks are recommended for influenza and respirators for TB in the national policy documents (24, 25).

Varying practices around the use of facemasks/respirators at the facility level might be due to two main reasons: (1) conflicting guidance from the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and (2) the availability of the certain type of masks/respirators in the hospitals. We have previously identified that low resource countries style their national recommendations on those given by the WHO or the CDC (12). Polices and guidelines of the WHO and the CDC are also not uniform for various infections, such as pandemic influenza, MERS-CoV and EVD (9, 26-29). Due to the conflicting guidance by the WHO and the CDC, HCWs used various types of facial protective equipment during the influenza A (H1N1) pdm09 pandemic (30). The same controversy is ongoing for EVD and various types of facemasks/respirators are being used due to inconsistent guidance from the health organisations and countries (4). The availability of certain types of facemasks and respirators in the hospital also determine their use and HCWs particularly in the low resource countries have to rely on what is provided by the hospitals (31).

Although respirators are reported to be more protective than the medical masks (13, 14), few hospitals in this study reported using respirators and amongst those that did, adherence with comprehensive respiratory protection programs (i.e. respirator

certification, medical evaluation, training and fit testing) appeared to be low (32). The use of respirators is generally limited in low resource countries due to direct cost of respirators and the indirect cost of certification, medical evaluation, training and fit testing procedures (31). There are no regulatory standards in low resource countries to certify the respirators to be used by HCWs, such as 29 CFR 1910.134 in the US (19), European Norm (EN) standards in Europe (33) and AS/ NZS 1716 in Australia (20). Medical evaluation should be part of the respiratory protection program to ensure that employees are medically fit to use a respirator and it is not harmful to the employees. Fit testing is also necessary to ensure the efficacy of a respirator, because a loosely fitted respirator may not perform better than a medical mask (34). Both qualitative and qualitative fit tests should be performed to examine and estimate the leakage around the face (35). Like previous studies, this study also showed that hospitals do not comply with the fit testing procedures (36).

Our data suggest that HCWs use facemasks and respirators for various lengths of time. Currently there are very little data available regarding the duration a facemask or respirator should be used for in the health care setting (5). It is perhaps not surprising that most HCWs do not know the correct length of the time facemasks and respirators should be used (37). Further studies should be conducted to set the duration that these products may be safely used for.

We have documented that non-standard practices do occur at hospital level in the low resource countries, such as extended use and re-use of facemasks and use of cloth and paper masks. These practices generally occur due to unavailability of facemasks and respirators in health care facilities, especially during outbreak or pandemic situations. The use of PPE is expected to increase during outbreaks and pandemics and consequently facemasks/respirators may be only available to staff working in ‘high risk’ wards or departments (31). During the SARS outbreak, the CDC recommended that N95 respirators be used over multiple shifts in the event of shortages, only if the product was not visibly soiled or damaged (38). A shortage of medical masks and respirators was reported in

many US hospitals during the 2009 influenza H1N1 pandemic and re-use was practised (30, 39, 40). Although few participants reported shortage of medical masks, more than a quarter of them reported unavailability of N95 respirators (39). Around 42% of HCWs reused N95 respirators for multiple shifts and "standard practice" and "shortage" were two most cited reasons for re-use by the health managers (30). Most US hospitals implemented a re-use policy even before the depletion of stock, while other used the available stock first and then reused respirators (40). Therefore, the re-use of facemasks and respirators is not limited to low resource countries, but high income countries may also be compelled to follow these non-standardised practices during outbreaks and pandemics.

Due to the shortage of supplies, "re-use after decontamination" is a common practice in low resource countries, and HCWs apply various methods to clean facemasks/respirators (12, 31). Decontamination of medical masks and N95 respirators is usually not recommended as their material is degraded with standard decontamination methods (41). For HCWs who are re-using their cloth masks over the course of the shift or attempting to decontaminate cloth masks for use the next day, the occupational risk from influenza and other pathogens may be heightened. As re-use is a common practice in low resource countries, further studies should be conducted to explore methods to decontaminate facemasks. There is currently an urgent need to develop guidelines around these practices in-order to ensure that hospitals and staff members know when it is appropriate to reuse a mask or extend the use of a product. Generally extended use and re-use is not recommended due to risk of self-contamination and risk of infection. The CDC recommends that managers need to weigh the benefits against the risks and to prefer extended use over re-use in cases where it is deemed essential (42).

Currently there is no evidence around the efficacy of cloth and paper masks and their use may put HCWs at risk of acquiring infections (12). However cloth masks may be the only option for low resource countries, which may have limited ability to purchase respirators or medical masks (12). Paper masks may become wet easily so should not be used.

Further research should be conducted around the efficacy of various types of facemasks and respirators.

We identified that there is wide variation in the quality of facemasks/respirators being worn in selected countries. PFE testing is undertaken to check the resistance of particular type of facemask or respirator against the penetration of particles through the material (43). As to be expected, the penetration of particles was highest through the cloth mask samples, followed by the medical masks. High penetration of particles may also be due to fewer layers in facemasks. For example, particle penetration of medical masks collected from Punjab hospitals was very high (87%), which could be due to more use of two layer masks (40.7%), compared to Beijing and Hanoi. Previous studies on the filtration efficiency reported penetration values ranging from 0% to 99% for medical masks (median 40%) and 95% to 99.5% for respirators (44). We were surprised by the variability in the penetration levels amongst the respirators received. This was mainly due to lack of regulatory bodies in the low income countries such as NIOSH in the US (19). “European Norm (EN) standards” in the Europe (33) and “AS/ NZS 1716 standards” in Australia (20). Our data also suggest that the filtration efficacy of certified respirators was high (median 0.3%, range 0.1-0.7%) compared to the non-certified respirators (median 3%, range 0.1-30%).

This study has some limitations. First, we collected data from hospital administrators or infection control coordinators and did not authenticate the practices of HCWs through observation and other means. The actual practices of HCWs may be different from those reported by hospital administrators or infection control coordinators. Second, we collected data from selected hospitals of a geographical area that may not represent the whole country. Finally, we only performed PFE tests and could not able to perform other tests. The PFE test is mainly used to test filtration performance of medical masks and is not recommended to examine respiratory protection. A medical mask with a very high PFE may still have very low filtration efficiency when other N95 testing methods are used (45). In this study we aimed to examine the practices around the use of facemasks/respirators and did not include other PPE and administrative and

environmental control measures. Infection control measures are broadly categorized into administrative control, environmental control and use of PPE (9). Other infection control strategies, compliance, contamination during donning and doffing and other transmission modes are important potential confounders in facemask studies (44). Large scale studies should be planned to examine the role of facemasks compared with other control measures.

CONCLUSION

Countries have various practices around the selection and use of facemasks and respirators, which depend on available resources and local recommendations. In order to ensure proper use of facemasks and respirators in the health care setting, the policies and guidelines should be clear and uniform across the institutions. We recommend that standardization of policies and guidelines based on existing evidence and situations in the low resources countries should be considered while developing those recommendations. Non-standardised practices, such as extended use and re-use of facemasks/respirators and the use of cloth masks, are common in low resource settings, and could be a potential threat for HCWs. Further research should be conducted around the re-use of facemasks/respirators and efficacy of cloth masks should also be examined.

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CHAPTER 5: CURRENT PRACTICES AND BARRIERS TO THE USE OF FACEMASKS AND RESPIRATORS AMONG HOSPITAL BASED HEALTHCARE WORKERS (HCWs) IN VIETNAM

Paper status:

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Declaration

I certify that this publication was a direct result of my research towards this PhD, and that reproduction in this thesis does not breach copyright regulations.

Abrar Ahmad Chughtai (Candidate): 

RATIONALE OF THE STUDY

The selection and use of facemasks/respirators at the hospital level depends on various environmental, organisational and individual factors. After examining the policies at the health department level (chapters 2 and 3) and practices at hospital level (Chapter 4), I conducted two studies to examine the use of facemasks/ respirators at staff level (Chapters 5 and 6). In this chapter (first study at staff level), I examined knowledge, attitude and practices of HCWs towards the use of facemasks and respirators. Focus groups were conducted in one country and HCWs (doctors and nurses) from selected departments of major hospitals were invited to participate.

Research question:

What are the practices and perceptions of hospital-based HCWs regarding the use of facemasks and respirators?

CONTRIBUTION TO THE THESIS

This study identified organisational and individual factors affecting selection and use of facemasks and respirators at staff level. Participants' knowledge and perceptions regarding respiratory protection and practices are generally influenced by availability of products in the hospital, risk level and personal choice. Participants have mixed views regarding the extended use and re-use of facemasks and respirators. Some participants considered the practice to be safe whereas others believed that re-use placed them at risk of contracting an infection. The results of this study contributed to the development of recommendations regarding facemask use in low resource countries.

ABSTRACT

Background:

This study aimed to examine the knowledge, attitudes, and practices towards the use of facemasks amongst hospital-based health care workers (HCWs) in Hanoi, Vietnam.

Methods:

A qualitative study incorporating 20 focus groups was conducted between August 2010 and May 2011. HCWs from 7 hospitals in Vietnam were invited to participate.

Results:

Issues associated with the availability of facemasks (medical and cloth masks) and respirators was the strongest theme to emerge from the discussion. Participants reported that it is not unusual for some types of facemask to be unavailable during non-emergency periods. It was highlighted that the use of facemasks and respirators is not continuous; rather it is limited to selected situations, locations and patients. Re-use of facemasks and respirators is also common in some settings. Finally, some participants reported believing the re-use of facemasks, particularly cloth masks, was safe, while others believed that the re-use of masks put staff at risk of infection.

***Conclusions*:**

In low and middle income countries, access to appropriate levels of personal protective equipment (PPE) may be restricted owing to competing demands for funding in hospital settings. It is important that issues around re-use and extended use of medical masks/respirators and decontamination of cloth masks are addressed in policy documents in order to minimize risk of infection.

INTRODUCTION

Protection of healthcare workers (HCWs) from communicable/respiratory infections is essential to promote the health and safety of staff and to maintain the functioning and capacity of the health care workforce during outbreaks of emerging infections, such as pandemic influenza, Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Ebola Virus (1-3). Infection prevention and control in health care settings involves, among other measures, the use of personal protective equipment (PPE), which encompasses all of the specialized equipment worn by HCWs for protection against health and safety hazards including gloves, eye protection, head and shoe coverings and respirators/ facemasks (4, 5).

In low resource settings, where the incidence of infectious disease is high and the hospital environmental conditions are often poor, hospitals may rely heavily on PPE to protect staff. The use of facemasks (including medical and cloth masks) and respirators is strongly recommended by the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) as a standard for transmission based precautions (4, 5). But even though this practice is highly recommended, actual policies and practices regarding the use of facemasks and respirators vary (6). For example, whereas the WHO and the CDC have the same policy on the use of facemasks/ respirators for seasonal influenza, tuberculosis, and Ebola virus infection (4, 7-11), they have different recommendations for pandemic influenza and MERS-CoV (4, 12, 13). Low and middle-income countries generally adopt policies and guidelines of the WHO, and/or the CDC (6). The problem is that low resource countries might not have the ability or finances to adopt infection control policies and respiratory protection guidelines equivalent to those originating from high resource countries. Therefore many non-standardised practices, such as the extended use and the re-use of facemasks, are common in the low resource countries. However, data on these practices are limited. Moreover, although cloth masks are commonly used in low resource countries, they are rarely mentioned in infection control policies and guidelines (14).

The appropriate use of facemasks and respirators is important to provide the desired level of protection; however, it requires knowledge, training and supervision. Compared with other types of PPE, adherence with facemask and respirator use is traditionally low, despite expert recommendations (15). During a sustained national/international outbreak of a novel viral respiratory infection, health systems may be overwhelmed and existing infection control plans undermined. In 2011, the Institute of Medicine of the US National Academy of Sciences recommended further research into the effectiveness of facemasks/respirators and the factors affecting individuals' willingness and ability to comply with recommendations regarding PPE use (16).

The current study aimed to examine knowledge, attitudes, risk perceptions and practices regarding the use of facemasks and respirators and barriers to compliance among hospital-based HCWs in Hanoi, Vietnam.

METHODS

Study design

A qualitative study incorporating 20 focus groups was conducted in Hanoi, Vietnam between August 2010 and May 2011. Ethical approval was obtained from the National Institute for National Institute of Hygiene and Epidemiology in Vietnam and the University of New South Wales in Australia. Seven hospitals were purposely selected based on their location and size. Both central (funded nationally) and city (funded by the city of Hanoi) hospitals were included. HCWs (physicians and nurses) from selected departments within these hospitals in Hanoi were invited through advertisements and snowball technique. Purposive samples were obtained from physicians and nurses from various departments to ensure diversity. Departments were selected on the basis of risk of repeated and multiple staff exposures to viral respiratory infections.

A total of 20 focus groups with 10 to 12 participants per group were conducted. Separate focus groups were arranged for physicians (10 focus groups) and nurses (10 focus groups) to avoid bias owing to dominant participation and professional influence (17). All focus groups were of mixed sex and were fairly homogenous with respect to the age. Three

focus groups were conducted by a different facilitator and were excluded, whereas the remaining 17 focus groups conducted by the same facilitator were included in the analysis. Each participant was provided with a modest incentive in the amount of US$5 to compensate for time.

Data collection

An interview guide was developed collaboratively by study researchers from Vietnam and Australia during an in-country workshop. Questions were designed to cover key areas of interest including personal risk perceptions, perceptions of importance and effectiveness of different infection control measures, current practices regarding the use of PPE (with a focus on facemask/respirator use), factors affecting compliance, and organizational practices and support around infection control practices. Before the workshops, an information sheet was provided and participants were asked to provide written informed consent. The focus group sessions ranged in duration from 60 to 90 minutes and were conducted in the Vietnamese language. During the sessions, the moderator's interaction with the group consisted primarily of delivering the main open ended questions, ensuring that the discussions remained relevant to the aim of the study, and encouraging all participants' involvement in the discussions. Group sessions were digitally recorded and transcribed in Vietnamese using standard word processing software, then translated into English.

Analysis

Thematic analysis was carried out and a group approach was taken to analyse transcripts to reduce bias and to ensure data rigor. Initially two investigators (AAC and HS) developed a code list of themes after a preliminary analysis of one-quarter of the transcripts. An agreed-upon thematic framework (consisting of main issues related to the facemasks use) was then applied to another subsample of transcripts and modified further. Identical themes were grouped into four major thematic categories. Using this final framework, one researcher (AAC) coded and analyzed all 17 transcripts. Coded text was organized within the identified themes of the developed framework. NVivo software (Pty Ltd. Version 10,

2012 QSR International Melbourne, Australia) was used to facilitate data management and analysis. Themes were described and variations in opinions were discussed. Anonymous quotes were narrated to describe the chosen themes.

RESULTS

Best protection method

Facemasks and respirators were considered an effective approach of preventing respiratory infections. Most participants described facemasks/respirators as the *"only"* and the *"best protection"* method available to protect HCWs from respiratory infections. Participants had mixed views on the level of protection afforded by the various types of products available, however. N95 respirators were considered the most effective, although most nurses emphasized that they had never used N95 respirators in their workplace, whereas some doctors remarked that N95 respirators were only available during emergencies. Both medical and cloth masks were described as being *"comfortable"*, and *"easy to breathe"* through. Medical masks were associated with being *"safe"*, *"effective"*, *"airy"* and *"clean"*, whereas cloth masks were *"soft"* and *"cheap"*. Some of the negative aspects associated with medical masks included that they are "e*xpensive*" and can be "*saturated with sweat*", whereas cloth masks are *"difficult to tie"* and *"dirty"*. There is a perception that medical masks are of better quality than cloth masks, despite the fact that medical masks are not subject to regulatory standards in Vietnam.

"I think medical masks protect more than cloth masks because they are made according to medical standards" (Physician).

Wearing multiple facemasks was reportedly a common practice among HCWs. Participants reported that wearing 2 or 3 medical masks together (on top of one another) is not usual. However, this practice is dependent on the type and availability of facemasks on the ward. Perceived thickness of the layer of facemask protection appeared to be an important factor.

"Medical masks are costly so they are often used limitedly. If the hospital can supply you with 5 fabric (cloth) masks a day, so would you like them more than the disposable ones?" (Nurse).

"I prefer medical mask because it makes me easy to breathe. If I need to use cloth mask for a long time in the emergency case, I feel very uncomfortable" (Nurse).

"I feel that N95 respirator is too stuffy. Sometimes, I am afraid of infection from the patients so I have to wear two facemasks together but then I feel stuffy" (Physician).

Issues around the type and availability of facemasks

"Availability" of facemasks in the hospitals was the strongest theme to emerge from the focus group sessions. Participants emphasized that it is not unusual for some types of facemasks to be unavailable during non-emergency periods. A shortage of facemasks was reported in many hospitals by both physicians and nurses. The type of product used is extremely dependent on what is provided by the hospital. Medical masks are not always available and in some instances only cloth masks are supplied to HCWs. At some sites, participants spoke of receiving only three cloth masks per year, with staff members responsible for 'decontaminating' them after each use.

"The hospital now stops providing medical mask. Sometimes, we ask but they don't provide" (Physician).

"The facemask is not enough for the staff, especially in the morning that is crowded of patients"(Nurse).

"When the medical masks are finished, I use cloth masks" (Nurse).

It was reported that N95 respirators are not routinely supplied in most hospitals or are provided to HCWs only in emergency department (ED) and intensive care units (ICUs) or in limited quantities during outbreaks and epidemics.

"N95 masks are in limited supply so we seldom use them. We can't afford to change several N95 respirators a day. Because of inadequate supply, we aren't really interested in

using them, except those who are very much conscious of their health and safety, so they are wearing N95s most of the time" (Physician).

"Self-purchase" was an important sub-theme related to facemask availability. In some settings, owing to the limited supplies of facemasks provided by hospitals, staff members reported buying their own supplies from local stores. Medical masks were the most common type reportedly purchased by HCWs, whereas extra cloth masks were purchased by some. In some instances, HCWs reported being unable to afford to buy extra facemasks themselves owing to low salaries and they need to rely on what was provided by the hospital. Some participants mentioned pharmaceutical companies as another source of facemasks and respirators.

"We want to wear facemask regularly but the quantity is not enough so we have to buy with our own money" (Doctor).

"Cloth masks are provided by hospital while we buy medical mask with our own money" (Nurse).

Patients, locations and situations: factors associated with facemask use

Participants highlighted that the use of facemasks/respirators is not continuous; but rather it is limited to select situations, locations and patients. Facemasks were commonly used while in contact with patients or items in the patient's room and during high risk situations or with some categories of patients (*"doing procedures", "changing transfusions"*, and *"examining new patients that I haven't known before"*). Exposure to patients perceived to be highly infectious (e.g. those with TB or pandemic influenza) was another factor influencing facemask use. The number of facemasks used per day also varied among participants and depended on the type of facemasks being used and their availability. HCWs reported typically using one to two medical masks per day; however this number varied depending on the ward/department.

"In the department of infectious diseases, we use the facemask all day during an epidemic because the diseases are easily transmitted through respiratory system. When there is no

epidemic, we have no feeling of disease transmission so we just use facemask with tuberculosis patients" (Physician).

"The risk is less in the Gastroenterology Department because few patients have a cough. For example, there are many virus and respiratory diseases in the infectious diseases department, so they must wear the facemasks. The medical staff must wear them in the emergency department and intensive care unit in the working hours" (Nurse).

Participants reported that facemasks and respirators are not generally worn while in the administration section or staff office or when walking the corridors.

"But when I move to work in intensive care unit and if I know there is a child with acute respiratory infection, meningitis or epidemic of influenza, H1N1, I certainly have to use facemask and sometimes I walk stealthily into the room. It means that depends on specific characteristics of work, I think so. How I can wear facemask when treating a diabetic patient" (Physician).

Interestingly, participants also emphasized that facemasks and respirators generally are not worn in the paediatric wards owing to staff concerns about frightening children.

"Another example, a crying child comes to the clinic and sees a doctor wearing a facemask, he or she is likely to be more scared and cry louder. Thus, adherence to wearing a facemask is not always done although I know I am exposed to respiratory infections" (Physician).

"You must wear the facemask in the surgical ward and the intensive care unit but it's unnecessary to wear in the paediatric ward because the adults with the masks and the glasses will make the children nervous" (Nurse).

Participants also suggested that facemasks are also not typically worn when talking with patients' family members and caregivers, as these people are considered to be healthy and there is the concern that facemask use "*hurt their feelings*". A few participants even felt that it was "*unfriendly*" to wear a facemask while having a short conversation on the

ward with patients, because patients may feel "*discriminated against*" and become "*hostile*".

"It would be impolite to use a facemask while giving instructions to patients or answering their questions" (Physician).

"For example, after going out the office, the patient comes and asks questions from me; it is not good to put the facemask on. If I put the facemask on, the patient will feel that I am unfriendly. He will think that I'm scared of being infected" (Nurse).

Facemask use as "source control" (i.e. used on a sick patient) was reported as well. One participant reported using a facemask when ill, to avoid transmitting infections to colleagues and children, whereas others reported that patients and/or their family members commonly use facemasks. Some participants believe that facemask use by patients is more important than by HCWs. Higher compliance by patients relative to HCWs was reported.

"Doctors are wearing facemasks while examining patients but they don't wear facemasks when coming back to their offices. Patients and their family members are wearing facemasks most of the time" (Physician)

"In my ward, all patients must wear facemask but the doctors do not have to wear one" (Physician)

Participants characterized facemask/respirator use as "*instinctive*", "*habitual*", or a "*routine*" practice. Several pointed out that facemask use increases significantly during outbreaks, pandemics and other high risk situations. This theme was reported more frequently in the nurse focus groups compared to the physician focus group.

"Certainly, it becomes instinctive. We are obligatory to wear a facemask before coming to a patient's room. If a patient calls while we are eating, we must wear a facemask to go to the patient. It's compulsory for all nurses here. Sometimes, patients call while we are sitting in office, we would take the facemask from a pocket immediately as a quick response" (Nurse).

"Because it is the infectious hospital, so it has become a habit to wear a facemask when entering patient rooms. Nobody enters a room without a facemask" (Nurse).

Re-use of facemasks

There were mixed views regarding the re-use of facemasks and respirators. Some participants considered the practice to be safe (mostly nurses) whereas others believed that re-use placed them at risk of contracting an infection (mostly physicians). Reasons given for not supporting re-use included that participants considered it "*unsafe*", "*unreliable* "and "*time consuming*". Nonetheless, re-use was reported as a common practice by nurses and doctors in all wards/departments and across all hospitals.

"I often wear the medical masks and never wear the cotton masks because the cotton mask is not up to the standard. I am afraid of washing and then drying them because it wastes time. Moreover, the water may contain E. coli so washing masks is unreliable" (Physician).

Some participants (mainly Physicians) highlighted that they would support the re-use of cloth masks if they did not have to be responsible for cleaning them.

"The only inconvenience I found in cloth masks is they have to be washed. Just think how many times a week I can wash it, how many times I have to take it off, and then re-apply it within a work day. Moreover I have to wash it at the end of the day and hang it out to dry – not to mention, if it rains I won't have a facemask for the next day. Too much for me" (Physician).

"If there is one person (staff member) who washes and sterilizes cloth mask we would prefer the use of a cloth mask" (Nurse).

Cloth masks were the most commonly re-used type, however participants also reported that medical masks and respirators are re-used after 'washing'. Participants emphasized that they preferred using a washed N95 respirator over a medical or cloth mask. Different approaches to 'cleaning' cloth masks were reported, including hand washing in a basin, washing in the hospital laundry, and sterilization by autoclaving or UV light exposure.

Some participants also reported taking their masks home and washing them with their domestic laundry.

"I wash by myself. After washing, I put all masks in a box and send them to the infection control department for sterilization" (Nurse).

"A washed and re-used N95 respirator is better and more effective than a medical mask" (Physician).

DISCUSSION

Our data reveal mixed practices regarding the selection and use of facemasks and respirators by HCWs in hospitals in Hanoi, determined primarily by the type of products available in the hospitals. Perceived risks associated with working in a particular ward or dealing with particular patients were the primary factors influencing facemask use. The main factors reported as barriers to facemask use appeared to be social (i.e. not wanting to offend patients or their family members) and attitudinal (i.e. not wanting to frighten children). The literature indicates that HCW compliance with facemask use is influenced by individual (risk perception and presence of adverse events) and organizational factors (availability, education and policies) (18, 19). Providing feedback on HCW adherence with precautions and regular communication with HCWs have been identified as important factors in facilitating their compliance with infection control practices (18).

Ensuring the availability of facemasks and respirators is essential to maximizing compliance. Of the issues raised by participants, the availability of medical masks and respirators was the most frequently identified issue. Participants spoke of inadequate supplies of medical masks and respirators resulting in staff having to re-use facemasks over one or more days. Finally, the use of cloth masks was also reported as routine practice and in some settings as the sole type provided by the hospital. In some hospitals, reported only three or four new cloth masks are provided to staff each year and it is the HCWs' responsibility to maintain their own supply of facemasks. This situation is of concern given that previous studies have identified an association between adherence to respiratory protection and the availability of facemasks in hospital settings (18).

The need for HCWs to purchase their own facemasks from local stores was another issue of concern identified by our participants. Generally, facemasks are bought from local stalls or shops that surround the hospital and are manufactured locally. These products may be of inferior quality and may provide a false sense of protection. The ability of facemasks to filter particles varies significantly depending on the material used for facemask construction. In the United States, the Food and Drug Administration (FDA) oversees the sale and marketing of medical devices, including medical masks, and recommends that manufacturers demonstrate medical mask performance in four areas: fluid resistance, filter efficiency, differential pressure, and flammability (20). At present, there are no data on the performance of locally purchased facemasks in these four areas. Samples of medical and cloth masks, collected from a Vietnamese hospital during a recent survey, demonstrated wide variations in filtration performance (data not shown).

Generally masks are recommended and used to protect HCWs from splashes or sprays of blood and body fluids and from droplet infections such as influenza. Respirators are designed for respiratory protection and properly fitted respirators provide better protection than masks (21, 22). The direct costs of buying respirators and indirect costs of certification, training and fit testing are high, however our data suggest that most hospitals do not use respirators. Estimates show that for a pandemic with an approximate estimated duration of 120 days, each HCW would need a total of 480 respirators. This would equate to an estimated cost of $302 per staff member (estimated cost of $0.63 per N95 respirator for products manufactured by a leading international company) or US$151,000 per hospital (for 500 Physicians/Nurses working in 'high risk wards/departments') (23). Although these are hypothetical calculations and do not take into account local pricing/discounts, it is unlikely that hospitals in low resource settings would have the capability of supplying the required quantities of facemasks during a pandemic or extended outbreak.

Our data indicate that the use of cloth masks is common among HCWs in Hanoi. Moreover, some participants expressed a preference for cloth masks because of perceived superior protection associated with thicker material than the commonly available medical

masks and the option of cleaning them with simple decontamination methods. There is a lack of information on the efficacy of cloth masks, as well as on such practices as double-masking (14). Regulatory standards require that masks do not permit blood or other potentially infectious fluids to pass through to or reach the wearer's skin, mouth or other mucous membranes under normal conditions and for the duration of PPE use. (24). In a report by a US National Institutes of Health Committee on the development of reusable facemasks for use during an influenza pandemic, committee members were hesitant to discourage the use of cloth masks but suggested caution with their use (24).

Our data also indicate that commercially available medical masks and respirators are currently being used for extended periods and/or are being re-used over multiple days. Medical masks and respirators have a limited life span. Once worn, they can become damaged, deformed or develop intolerable levels of breathing resistance from moisture build-up. If worn in an environment with a high probability of exposure to infectious agents, they can become contaminated, especially if worn in a room with any type of aerosol generating procedure (24). Commercially available disposable medical masks and respirators are not designed for re-use, and there is nearly universal agreement that re-use, even by a single user, should be discouraged except in the most extreme circumstances. Health care facilities may be able to extend the use of medical masks and respirators by training personnel to wear them during serial patient encounters without removing or re-donning between encounters. The CDC cautiously recommends the extended use and re-use of facemasks in case of high demand and/or unavailability of masks/respirators taking into account the severity of infection, transmission mode, spread of disease and risk of self-contamination (25). The precise balance between the risk of contact transmission and the benefit of extended use is unknown, although the risk is minimized if HCWs perform hand hygiene every time before and after touching the respirator.

Various approaches to 'cleaning' disposable medical masks and respirators were reported including autoclaving, isopropyl alcohol, bleach, hydrogen peroxide, microwave, soap and water, UV radiation and dry heat. The effectiveness of these decontamination measures is

uncertain, no single technique is recommended by either the WHO or the CDC. Any method of decontaminating a facemask must remove the viral threat, be harmless to the user, and should not compromise the integrity of the various elements of the facemask (e.g., tear or deform the filter, stretch the elastic attachments, bend the nose clip) (24). More research is needed to ascertain whether any of the methods can be used, given that the material of commercially available medical masks and respirators is not suitable for re-use after standard methods of decontamination (24).

Considering the limited resources in low and middle income countries, the issues surrounding the use of cloth masks and extended use and decontamination of facemasks need to be addressed to inform pandemic preparedness. Current guidelines underlying effective control programs have been produced by high-income countries for their own social, economic, and health environments (6). Low and middle income countries might not have the ability to adopt these principles using the same methods and materials. As highlighted by Zimmerman in 2007, there is a need for the development of infection control and prevention guidelines based on evidence but adapted to the specific needs of HCWs in low resource settings (26). For example, recent WHO infection control guidelines discuss the level of evidence and also briefly discuss the use of cloth masks (4). Further studies are needed to examine the efficacy of various decontamination techniques and HCWs should be educated about these practices.

The use of focus groups is the strength of the present study, allowing a significant depth of exploration into the behavioural aspects of a research area dominated by quantitative analyses of facemask efficacy and filtration capacity. The study also has several limitations, however. Member checking of themes was not undertaken. The fact that focus groups were conducted in the Vietnamese language and then translated into English might have jeopardized the interpretation and completeness of data. This was a small study and the study's qualitative nature restricts the generalizability of our results. Facemask use varies among countries and a study in one country might not be applicable to rest of the world. Interviews were only undertaken with a select group of participants, so the possibility of other important themes emerging cannot be ruled out. Finally,

participants may have over-reported compliance with infection control measures to avoid judgment resulting in social desirability bias.

In summary, this study has identified considerable variation in the selection and use of facemasks by hospital HCWs, along with various re-use practices. It will be important to gather evidence from other settings on the use of non-standard practices by HCWs identified here to enable the updating of guidelines to address common practices in low income settings. Policies and guidelines should address critical areas, such as duration of facemask use, extended use and decontamination methods. Future research on the cost-effectiveness of providing PPE to HCWs in low income settings will be important as well.

CONFLICT OF INTERESTS

C.R.M. receives funding from vaccine manufacturers GSK and bio-CSL for investigator-driven research. C.R.M. has held an Australian Research Council Linkage Grant with 3M as the industry partner, for investigator driven research. 3M have also contributed supplies of masks and respirators for investigator-driven clinical trials. H.S. held a National Health and Medical Research Council Australian-based Public Health Training Fellowship at the time of the study (1012631). She also has received funding from vaccine manufacturers GSK, bio-CSL, and Sanofi Pasteur for investigator-driven research and presentations. L.M. is supported by the award of a National Health and Medical Research Council Senior Research Fellowship (Elizabeth Blackburn Fellowship, Public Health). The Kirby Institute received funding from the Australian Government Department of Health and is affiliated with the Faculty of Medicine, University of New South Wales. The remaining authors have no conflicts of interest to declare.

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AUTHORS' CONTRIBUTION

A.C. was responsible for the data management, analysis and preparing a draft of the manuscript. H.S. contributed in the study design and data analysis. R.M. contributed to study design and manuscript review. T.C.D. and P.T.N. assisted with data collection and translation. L.M. assisted with study design and facilitator training. All authors reviewed the final version of the manuscript.

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CHAPTER 6: FACTORS AFFECTING COMPLIANCE OF HEALTHCARE WORKERS WITH THE USE OF FACEMASKS

Paper status:

The following paper constitutes chapter 6 of the thesis and has been submitted to the Journal.

Chughtai AA, Seale H, Dung TC, Hayen A, Rahman B, MacIntyre CR. Factors affecting compliance of healthcare workers with the use of facemasks. Unpublished work. 2015

Declaration

I certify that this publication was a direct result of my research towards this PhD, and that reproduction in this thesis does not breach copyright regulations.

Abrar Ahmad Chughtai (Candidate): 

RATIONALE OF THE STUDY

The compliance of health care workers (HCWs) with various infection control precautions, particularly with personal protective equipment (PPE), is reported to be low. The use of facemasks is considered most bothersome item among PPE and compliance with the use of facemasks is also low compared to other PPE. In this chapter (second study at HCW level), I examined factors associated with the compliance amongst hospital HCWs with the use of various types of facemasks.

Research question:

Which factors are associated with the compliance and use of facemasks among hospital-based HCWs?

CONTRIBUTION TO THESIS

This study shows that the compliance with the use of facemasks is low and it decreases with time. I also identified individual and organisational factors associated with the continuous use of facemasks among HCWs. Commonly reported adverse events with facemask mask use are presented and discussed in detail. On the basis of the results, I proposed strategies to improve compliance of HCWs with respiratory protection.

ABSTRACT

Background:

The use of facemasks is recommended in health care settings to prevent the spread of infections and to protect staff members. Compliance with the facemask use is thought to improve respiratory protection. The aim of this study was to examine the factors associated with the compliance amongst hospital healthcare workers (HCWs) with the use of facemasks.

Methods:

Compliance with medical masks and cloth masks was measured over a four week period within the setting of a randomized controlled trial (RCT) in Hanoi, Vietnam. Compliance with the use of facemasks was monitored through the use of daily diary cards. HCWs were instructed to record their daily activities in diary cards. Demographic, clinical and diary card data were used to determine the predictors of compliance with the use of facemasks in the health care setting and the relationship of compliance with infection outcomes.

Results:

Compliance rates for both medical and cloth masks decreased over time during the four weeks: medical mask use decreased from 77.1% to 68.0% (p value <0.001) and cloth masks from 78.4% to 69.3% (p value <0.001). In a multivariable analysis, the presence of adverse events (adjusted RR 0.90, 95% CI 0.85-0.95), contact with febrile respiratory illness patients (adjusted RR 1.14, 95% CI 1. 07-1.20) and performing aerosol generating procedures (adjusted RR 0.78, 95% CI 0.73-0.82) were significant predictors of compliance. There was no difference in compliance levels between cloth and medical mask use (adjusted RR 1.02, 95% CI 0.97-1.08).

Being compliant with the facemask use (average use equal to or greater than 70% of working time) was not associated with clinical respiratory illness (CRI), influenza like illness

(ILI) and laboratory-confirmed viral respiratory infection. Rates of CRI were 6.9% and 5.2% in compliant and non-compliant groups respectively (RR 1.32, 95% CI 0.83 to 2.12) and the rates of ILI in the two groups were 1.7% and 0.6% respectively (RR 2.80 and 95% CI 0.79 to 10.00). Four percent of HCWs in the compliant group and 4.8% of HCWs in the noncompliant group had laboratory-confirmed viral respiratory infection (RR 0.83, 95% CI 0.48 to 1.43).

Conclusion:

HCWs using both cloth and medical masks continuously over a period of time showed decreases in compliance over a four week period. Compliance with facemask use might be associated with a perceived risk of acquiring an infection. Understanding the factors that affect compliance is important for the occupational health and safety of HCWs.

BACKGROUND

It is well documented that compared to the general population, hospital health care workers (HCWs) are at increased risk of acquiring various nosocomial respiratory infections (1, 2). In addition, studies have shown that HCWs are responsible for contributing to the spread of pathogens in health care facilities, especially during outbreaks and pandemics (3, 4). To prevent the spread of infections and to protect staff members, most countries recommend the use of facemasks (including medical and cloth masks) and respirators in the health care setting (5). The compliance of HCWs with the use of facemasks is therefore important to protect the health care workforce and prevent the spread of respiratory pathogens. It has been previously suggested that HCW compliance with facemasks depends on various individual, organizational and environmental factors (6-10).

Compliance with the use of personal protective equipment (PPE), including facemasks, has been shown to vary among HCWs (6, 11). Compliance with the use of facial protective devices is lower compared to other PPE (12-14). A systematic review of PPE studies showed that the compliance with the use of facemasks ranges from 4% to 55% (mean 30%) (15). Facemask use is also recommended as a component of standard precautions to minimize the risk of splashes and sprays of blood or body fluids on the face (16, 17). However, studies show that only 5-10% of HCWs use masks during trauma resuscitation (13, 14) and less than half (46%) use masks during other high risk procedures with trauma cases (11).

Suboptimal compliance with respiratory protection is reported not only during routine care but also during outbreaks and pandemic situations (18-21). During the SARS outbreak in Canada, around 28% of nurses did not use masks/respirators when entering a SARS patient's room (18). Among the HCWs who cared for SARS patients in the United States, 44% did not use masks and 48% did not use respirators (19). Another study from the US reported that among the HCWs infected by influenza A(H1N1)pdm09 virus, only 20% used

masks or respirators all time (20). A study in South Korea reported a low compliance among those HCWs infected with influenza A(H1N1)pdm09 virus, and only 30% of HCWs used medical masks and 23% used respirators regularly (21).

This study aimed to examine the individual, organizational and environmental factors associated with facemasks use and compliance amongst hospital HCWs and examine the relationship of compliance with infection outcomes.

METHODS

Compliance with the use of facemasks was measured over a four week period within the setting of a randomised controlled trial (RCT) in Hanoi, Vietnam(22). 1149 HCWs who either used a medical mask (n=580) or a cloth mask (n=569), were included in the study. Demographic and clinical data were collected, including age, sex, occupation, smoking history, influenza vaccination and pre-existing medical illness. During the four weeks, compliance with the use of medical and cloth masks was monitored through the use of diary cards. HCWs were instructed to record their daily activities in the diary cards. Information collected included the number of hours worked, number of hours that they wore a facemask, number of febrile patents seen, hand washing practices and conduction of aerosol generating procedures (AGPs).

At the end of the study, the participants completed an exit survey and provided information on adverse events and perceived risk of infection. Demographic, clinical, exit interview and diary card data were used to examine factors associated with HCW compliance with the use of facemasks.

Study and outcome factors

The primary outcome measure of this study was self-reported HCW compliance with the use of facemasks over the four week trial period. HCWs recorded the number of working hours and number of hours that they wore a facemask in diary cards at the end of each day. To measure compliance, a continuous variable was created by dividing the average

hours of facemask use over the four week trial period by the average number of working hours over the same period ("Outcome 1"). Holidays and other nonworking days were excluded. A binary variable was created to examine the factors affecting compliance ("Outcome 2"). HCWs were categorised as "compliant" if the average use was greater than or equal to 70% of the working time. This cut off estimate has been used in our previous published mask study (8).

HCWs were categorised as being in "contact with febrile respiratory illness patients" if they reported that they examined at least one febrile respiratory illness patient per day during the trial period. The mean of the number of self-reported hand washes performed by a HCW over the trial period was calculated. The mean of all AGPs performed over the four week trial period was estimated by self-report, and a binary variable "aerosol generating procedures" was created if HCWs performed at least one AGP per day during the trial period (1). AGPs were defined as procedures which generate respiratory aerosols, such as suctioning of airways, sputum induction, endotracheal Intubation, chest physiotherapy, positive airway pressure (BIPAP) and bronchoscopy. HCWs reported various adverse events during the study period, such as headache, skin rash, breathing problems, allergies and general discomfort. A binary variable "presence of an adverse event associated with facemask use" was created if any adverse event was reported by a HCW.

Analysis

Longitudinal analysis was performed to examine the trends of the facemasks use over the four week period. To account for the correlation of compliance and study period for HCWs, we used mixed models (PROC MIXED) with a random intercept and slope (23). The continuous compliance variable ("Outcome 1") was used for the longitudinal analysis.

A multivariable log binomial model was fitted using Generalised Estimating Equation (GEE) to estimate relative risk (RR) of being compliant at least 70% of the time after adjusting for potential confounders (24). As hospital wards were the unit of randomisation, we made

an adjustment for clustering by wards. A binary compliance variable was the outcome measure ("Outcome 2") for regression analysis. First, univariable analysis was conducted with the main exposure variable (randomisation arm) and all other important variables. Any variable that had a p value <0.25 in the univariable analysis was included in the multivariable analysis. A backward elimination method was applied and variables that did not have any confounding effect were removed from the final model. Data on self-reported adverse events for 19 HCWs were missing and these cases were excluded from the final model. Distribution of the 19 missing cases was generally similar between study and outcome factors. The data was analysed using SAS, version 9.4.

As pre-existing medical illnesses and self-reported adverse events (such as discomfort) were significant predictors of compliance in the univariable analysis, we performed an additional analysis to examine the nature of HCW illness and type of adverse event associated with compliance. Compliance rates were estimated among HCWs with pre-existing medical illnesses and among those who have reported an adverse event. Univariable log binomial models were fitted using GEE to estimate the relative risk of being compliant at least 70% of the time (24).

To examine the relationship of compliance with infection outcomes, we compared the rates of clinical respiratory illness (CRI), influenza-like illness (ILI) and laboratory-confirmed viral respiratory infection among compliant and noncompliant groups. Relative risk of CRl, ILI and laboratory-confirmed viral respiratory infection were calculated using the log binomial model under GEE framework.

Ethical approval

Ethical approval for this trial was obtained from the Institutional Review Board at the National Institute for Hygiene and Epidemiology (NIHE) (approval number 05 IRB) and the Human Research Ethics Committee of the University of New South Wales (UNSW), Australia, (HREC approval number 10306).

RESULTS

Table 6.1: Demographic characteristics

Variable	Number	Percent
Type of mask		
Cloth mask	569	49.5
Medical mask	580	50.5
Gender		
Male	245	21.3
Female	904	78.7
Age (mean and SD)		35.9 (± 10.6 SD)
Work type		
Doctor	341	29.7
Nurse	808	70.3
Work Year (mean and SD)		10.5 (±9.8 SD)
Education		
Postgraduate	213	18.5
Graduate	936	81.5
Smoking status		
Current/Ex. Smoker	157	13.7
Non smoker	558/992	86.3
Influenza vaccine		
Yes	42	3.7
No	1107	96.3
Pre-existing medical illness		
Yes	136	11.8
No	1013	88.2
Presence of adverse events		
Yes	469	40.8
No	661	57.5
Missing data	19	1.7
Contact with febrile patient*		
Yes	588	51.2
No	561	48.8
Hand washing per day (Mean and SD)		15.6 (±11.0 SD)
Aerosol generating procedures**		
Yes	768	66.8
No	381	33.2

** Examined at least one febrile respiratory illness patient per day during the trial period*

*** Performed at least one AGP per day during trial period*

Demographic characteristics of participants are detailed in Table 1. Among the 1149 HCWs in the medical and cloth mask groups, 21.3% (245/1149) were male, 29.7% (341/1149) were doctors and 18.5% (213/1149) had a post-graduate degree. The mean age of participants was 35.9 years (± 10.6 SD) and 3.7% (42/1149) of them had received influenza vaccine.

Figure 7.1: Regression line to show compliance of HCWs in Vietnam over the four week trial period

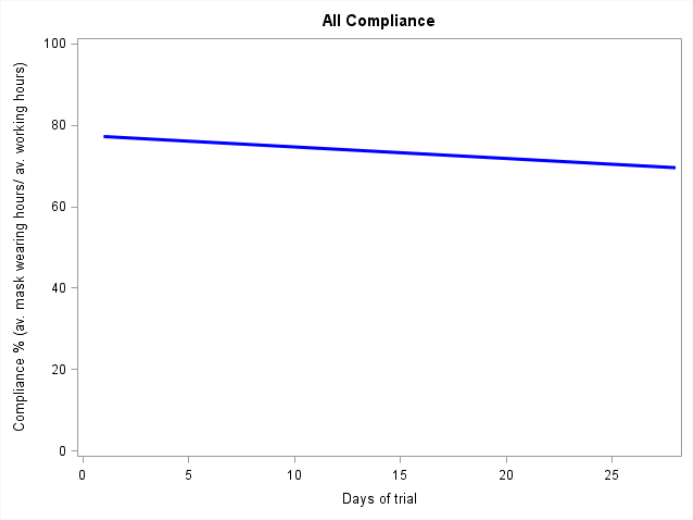
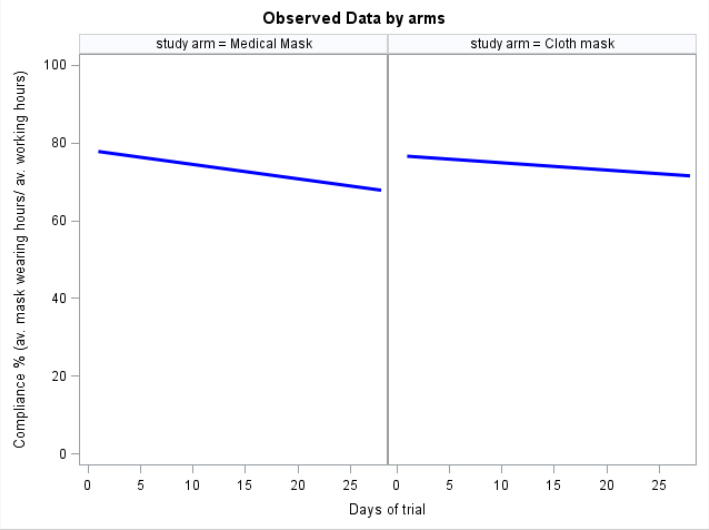


Figure 7.2: Regression line to show compliance of HCWs in Vietnam over the four week trial period in intervention arms



The longitudinal analysis showed that the compliance of HCWs with facemasks decreased within that time (Figure 1 and 2). Model based mean compliance rates (least square mean) were 73.7% and 72.4% for the cloth mask and medical masks, respectively. There were no differences in compliance between medical and cloth masks ($P = 0.155$) and the use of both types of masks decreased over the four week trial period. The compliance rate in the medical mask group decreased from 77.1 % on day 1 to 68.0 % on day 28 ($P < 0.001$) and the compliance rate in the cloth mask group decreased from 78.4 % on day 1 to 69.3% on day 28 ($P < 0.001$).

56.8% of HCWs (323/569) in the cloth mask group and 56.6% of HCWs (328/580) in the medical mask group used a facemask during 70% or more of their working time. The following variables were found to be a significant predictor of compliance during univariable regression analysis: age, pre-existing medical illness, adverse events associated with facemask use, contact with at least one febrile respiratory illness patient per day and performing at least one AGP per day (Table 2). Univariable analysis showed that older HCWs were more compliant with facemask use in our dataset (p-value 0.046). HCWs with a pre-existing medical illness were 18% more compliant than those without a reported medical illness (RR 1.18, 95% CI 1.03-1.35). Adverse events connected with mask use were associated with low compliance levels (RR 0.85, 95% CI 0.77-0.95). Participants who saw at least one patient with a febrile respiratory illness per day were 30% more compliant, compared to those who did not see a febrile patient (RR 1.30, 95% CI 1.17-1.44). Performing at least one AGP during the trial period was associated with 35% reduction in compliance (RR 0.65, 95% CI 0.69-0.71).

Table 6.2: Predictors of compliance with the use of facemasks - Univariable analysis

Variable	Compliance*		Univariate analysis		
	Number	%	RR	(95% CI)	P-value
Type of masks (Arm)					
Cloth mask	323/569	56.8	1.00	0.91-1.11	0.941
Medical mask	328/580	56.6	Ref		
Gender					
Male	134/245	54.7	0.96	0.84-1.09	0.491
Female	517/904	57.2	Ref		
Age			1.00	(1.00-1.01)	0.046
Work type					
Doctor	201/341	58.9	1.06	0.95-1.18	0.302
Nurse	450/808	55.7	Ref		
Work Year			1.00	(1.00-1.01)	0.604
Education					
Post-graduate	129/213	60. 6	1.08	0.96-1.23	0.187
Graduate	522/936	55.8	Ref.		
Smoking status					
Current/Ex. Smoker	93/157	59.2	1.05	(0.91-1.21)	0.472
Non smoker	558/992	56.2	Ref.		
Flu vaccine					
Yes	23/42	54.8	0.97	0.73-1.28	0.804
No	628/1107	56.7	Ref.		
Preexisting medical illness					
Yes	89/136	65.4	1.18	1.03-1.35	0.016
No	562/1013	55.5	Ref.		
Presence of adverse events**					
Yes	242/469	51.6	0.85	0.77-0.95	0.004
No	399/661	60.4	Ref.		
Contact with febrile patient***					
Yes	375/588	63.8	1.30	1.17-1.44	<0.001
No	276/561	49.2	Ref		
Hand washing per day			1.01	(0.96-1.05)	0.838
Aerosol generating procedures****					
Yes	368/768	47.9	0.65	(0.59-0.71)	<0.001
No	283/381	74.3	Ref.		

** HCWs were categorized as "compliant" if the average use was greater than or equal to 70% of the working time*

*** Missing data for 19 participants*

**** Examined at least one febrile respiratory illness patient per day during the trial period*

***** Performed at least one aerosol generating procedure (AGP) per day during trial period*

Table 6.3: Predictors of compliance* with the use of facemasks - Multivariable analysis

Variable	RR	(95% CI)	P-value
Type of masks			
Cloth masks	1.02	(0.97-1.08)	0.458
Medical masks	Ref		
Presence of adverse events**			
Yes	0.90	(0.85-0.95)	<0.001
No	Ref		
Contact with febrile patient***			
Yes	1.14	(1.07-1.20)	<0.001
No			
Aerosol generating procedure per day******			
Yes	0.78	(0.73-0.82)	<0.001
No	Ref		

** HCWs were categorized as "compliant" if the average use was greater than or equal to 70% of the working time*
*** Missing data for 19 participants*
**** Examined at least one febrile respiratory illness patient per day during the trial period*
***** Performed at least one aerosol generating procedure (AGP) per day during trial period*

Adverse events associated with mask use, contact with febrile respiratory illness patients and performing AGPs remained significant predictors of compliance during multivariable analysis (Table 3). After adjusting for other factors, compliance was significantly lower among those HCWs who reported an adverse event associated with the mask use (adjusted RR 0.90, 95% CI 0.85-0.95). Compliance was 14% higher in those HCWs who examined at least one febrile respiratory illness patient per day (adjusted RR 1.14, 95% CI 1.07-1.20). Finally, HCWs who performed at least one AGP per day during the trial period had 22% lower compliance compared to those who did not perform any AGPs.

2.6% (30/1149) of participants were asthmatic, 1.1% (13/1149) of participants were immunocompromised and 8.8% (101/1149) of participants had "other" medical illnesses. Compliance was significantly higher in HCWs who had asthma (RR 1.37, 95% CI 1.11-1.68) (Table 4). General discomfort and breathing problems were the most commonly reported adverse events. 35.1% (397/1130) of participants reported general discomfort and 18.3% of participants (207/1130) reported breathing problems. Compliance was significantly lower among participants who reported discomfort (RR 0.89, 95% CI 0.79-0.99) and breathing problems (RR 0.75, 95% CI 0.64-0.88) (Table 5).

Table 6.4: Compliance of the HCWs having medical conditions

Medical conditions	Compliance* Number (%)	RR**	(95% CI)	P-value**
Asthmatic				
Yes	23/30 (76.7%)	1.37	1.11-1.68	0.003
No	628/1119 (56.1%)	Ref		
Immune-compromised				
Yes	6/13 (46.2%)	0.81	0.45-1.47	0.490
No	645/1136 (56.8%)	Ref		
Other medical conditions				
Yes	64/101 (63.4%)	1.13	0.97-1.32	0.125
No	587/1048 (56.0%)	Ref		

** HCWs were categorized as "compliant" if the average use was greater than or equal to 70% of the working time*
***Un-adjusted RR and p-values*

Table 6.5: Compliance of the HCWs with an associated adverse event

Adverse effects	Compliance* Number** (%)	RR***	(95% CI)	P-value***
Headache				
Yes	37/80 (46.2%)	0.80	0.63-1.02	0.077
No	604/1050 (57.5%)	Ref		
Skin rash				
Yes	20/31 (64.5%)	1.14	0.87-1.49	0.329
No	621/1099 (56.5%)	Ref		
Breathing problem				
Yes	92/207 (44.4%)	0.75	0.64-0.88	<.0001
No	549/923 (59.5)	Ref		
Allergy				
Yes	8/20 (40.0%)	0.70	0.41-1.20	0.197
No	633/1110 (57.0%)	Ref		
General discomfort				
Yes	208/397 (52.4%)	0.89	0.79-0.99	0.035
No	433/733 (59.1%)	Ref		
Other				
Yes	15/26 (57.7%)	1.02	0.73-1.42	0.919
No	626/1104 (56.7%)	Ref		

** HCWs were categorized as "compliant" if the average use was greater than or equal to 70% of the working time*
****Missing data for 19 participants*
***Un-adjusted RR and p-values*

Exit interviews provided insight into the use of facemasks in various situations. Approximately 34% of participants (396/1149) believed that it is important to wear a mask for every patient and 50% (572/1149) believed that it is necessary to wash hands after

touching a mask. 22% of participants (250/1149) reported that it is difficult to communicate with patients when wearing a mask and 15% (174/1149) thought that it is "rude" to wear a mask when communicating with patients. Only 11% of participants (124/1149) reported that it is easy to forget to put mask on before having contact with a patient.

Compliance was not associated with clinical respiratory illness (CRI), influenza like illness (ILI) or laboratory-confirmed viral respiratory infection in this study (Table 6). Rates of CRI were 6.9% and 5.2% in compliant and non-compliant groups, respectively (RR 1.32, 95% CI 0.83 to 2.12) and the rates of ILI in the two groups were 1.7% and 0.6%, respectively (RR 2.80 and 95% CI 0.79 to 10.00). Four percent of HCWs in the compliant group and 4.8% of HCWs in the noncompliant group had laboratory-confirmed viral respiratory infection (RR 0.83, 95% CI 0.48 to 1.43).

Table 6.6: Rates of CRI, ILI and laboratory confirmed viral infections among compliant* and non-complaint groups

	Clinical respiratory illness (CRI) **No (%)**	**RR** (95% CI)**	**Influenza like illness (ILI)** **No (%)**	**RR** (95% CI)**	**Laboratory confirmed viruses** **No (%)**	**RR** (95% CI)**
Complaint	45/651 (6.9%)	1.32 (0.83 to 2.12)	11/651 (1.7%)	2.80 (0.79 to 10.0)	26/651 (4.0%)	0.83 (0.48 to 1.43)
Non-compliant	26/498 (5.2%)	Ref	3/498 (0.6%)	Ref	24/498 (4.8%)	Ref

** HCWs were categorized as "compliant" if the average use was greater than or equal to 70% of the working time*
***Un-adjusted RR*

DISCUSSION

We examined the factors associated with mask use compliance amongst a large group of HCWs who used facemasks over a period of four weeks. High compliance among HCWs

who have contact with febrile respiratory illness patients and among those with pre-existing medical illness shows that perceived risk of infection might influence the compliance and use of facemasks in the health care setting. The use of facemasks may be increased when perceived risk of infection is high. Compliance may decrease over time due to exertion and presence of adverse events associated with use of facemasks and design/material of facemasks should be improved for comfort and better acceptability. We were unable to show any association between compliance and infection – however, this could be explained by lack of protective efficacy of either cloth or medical masks. Our previous RCTs of face masks failed to show efficacy of medical masks (7, 8).

Previous studies have reported an increased use of facemasks in high risk situations, such as direct contact with infectious patients and working in high risk wards (14, 25-27). In this study, the use of facemasks was higher during contact with febrile respiratory patients. The use of facemasks in the health care setting also depends on pre-existing medical illnesses and immune status of HCWs (28). Increased facemask use in these situations might be due to perceived risk of infection and individual beliefs that are thought to be highly associated with the adoption of protective behaviour (29, 30). If risk is perceived to be high, the use of facemasks may be increased (31) and superior respiratory protection will be recommended (28). In a focus group discussion in the US after the H1N1 pandemic, the participants reported high compliance with the use of PPE during the initial phase of the pandemic, which was later reduced due to low risk perception and less severity of disease (32). Studies have shown that working in paediatric unit is associated with low facemask use due to low perceived risk of infection (25). On the other hand, facemasks are continuously used by HCWs to protect from Ebola due to easy-transmissibility and high case fatality. Medical masks were initially recommended for HCWs to protect from Ebola, however recommendations were changed in favour of respirators later on following the infection of two nurses in the US while using PPE (33, 34).

Low compliance during AGPs in this study is a new finding however it may be explained by using multiple layers of PPE in these situations. Wearing too much PPE may be associated

with more fatigue, exertion and adverse events (35). Moreover, the compliance variable was created by dividing the average hours of facemask use over by the average number of working hours over the same period and it is possible that HCWs used facemasks while performing AGPs but did not use them during remaining time. It may also be possible that HCWs who did AGPs were working in busier settings, were more time-poor, and therefore less likely to wear PPE.

Like previous studies, (7, 8) the compliance level decreased over time for both the medical mask and cloth mask arms. A decrease in compliance over time may be attributed to adverse effects of facemasks such as discomfort, which generally increase with wearing time and may be at peak after 8-12 hours (36). Facemask use is generally associated with more discomfort than other PPE (37). Despite the severity and high case fatality of SARS, exhaustion was a factor and people were more at risk after working long hour shifts and for many days. The presence of adverse events is related to the type, material and design of facemask and wearing time. Respirators are generally associated with more adverse events compared to medical masks (7, 8, 36), however we did not examine the use of respirators. Further studies should be conducted to improve the design and material of facemasks so that adverse events are reduced and comfort and compliance is improved, especially for HCWs working for long durations (38). Moreover, facemask use in hot and humid environments may lead to higher risk of dehydration, impaired professional performance and higher risk of infection (39). Facemask use should be tested in various environmental conditions so that they may be used over the long period of time without adverse events.

The overall compliance level was low and around half of the HCWs used a facemask equal or more than 70% of their working time. Previous clinical trials in health care settings reported varying compliance among HCWs (57% to 86%), depending on type of intervention and facemask used (7, 8). However, the compliance of HCWs in clinical trials may not reflect routine practice, where compliance is reported to be even lower (12-15). Organizational support is offered during clinical trials, including training, availability of

masks, and regular follow-up by supervisors, and evidence suggests that all these factors are associated with compliance among hospital HCWs (10). Facemasks may not be readily available in the hospitals in routine practice, particularly in low resource settings (27) and this may also result in low compliance (15, 40).

Individual attitudes and beliefs also play a role in accepting or rejecting certain behaviour. Like previous studies, our participants also reported difficulty in communication (37, 41) and interference with patient relationships, which might influence compliance (9, 42). However, very few of our participants reported a "tendency to forget", which is reported to be a major cause of low compliance in other studies (9, 40). Other reasons discussed in the literature for being non-compliant are: interference in patient care activities, time factors, problems in identifying patients and sense of isolation (13, 37, 40). Low compliance with hand hygiene and low vaccine uptake among HCWs also highlights the importance of behaviour change campaigns (43-46). Like previous studies, demographic characteristics did not predict compliance in our study (6, 10).

Compliance with the use of facemasks was not associated with infection risk in this study. The study may be underpowered to detect the difference due to small sample size and few cases of CRI, ILI and laboratory confirmed viruses. It may also be due to lack of efficacy of both medical and cloth masks. Respirators are generally considered more effective than facemasks due to tight seal around the face (7, 8).

There are some limitations in this study. We analysed self-reported data from the diary cards, collected over a period of four weeks. Self-reporting compliance is reported to be higher compared to the actual practices (9) and it may not be free from recall and other biases (47). Secondly, we examined compliance with the use of medical and cloth masks in this study and did not examine compliance with the other types of facemasks. For example, compared to medical masks, compliance with the use of N95 respirators is lower due to presence of adverse events (7). Respirators are typically made of polypropylene wool felt or fiberglass paper and the wearer draws air in through the filter creating

negative pressure inside the respirator, which can result in breathing problems and other adverse effects (16). Finally, we could not assess organizational support factors (e.g. training and monitoring), which improve compliance (10, 26, 48).

Most compliance studies are cross sectional and rely on participants or staff members self-reporting their compliance with mask use and adverse events. Only a few studies have explored the phenomenon in routine clinical care. Further studies should be conducted to examine the factors associated with compliance in routine practice, and to develop strategies for improvement of HCW compliance. Innovative strategies and new tools should be developed to improve compliance of HCWs with the use of respiratory protection devices. As HCWs tend to forget to use facemasks, regular communications and monitoring support should be provided at the organizational level. Various signs may be posted in the working area to remind HCWs to use facemasks and increase compliance (49).

CONCLUSION

HCWs have low levels of compliance with the use of facemasks, especially with increasing duration of use, which may jeopardize not only their safety but also the safety of people surrounding them. The continuous use of facemasks depends on various modifiable and non-modifiable factors. Exertion and adverse events associated with continuous use of facemasks and perceived risk of acquiring an infection appear to be the most significant predictors of compliance with the use of facemasks. Compliance rates may also be increased by improving the availability of and access to facemasks at organizational level. New strategies and tools should be developed to improve compliance of HCWs. Adverse events associated with facemasks may be the main reason for low compliance. Further studies should be conducted to improve the design and material of facemasks so that the wearer may experience less adverse events.

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CHAPTER 7: USE OF CLOTH MASKS IN THE PRACTICE OF INFECTION CONTROL–EVIDENCE AND POLICY GAPS

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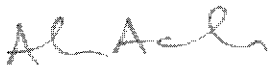
Declaration

I certify that this publication was a direct result of my research towards this PhD, and that reproduction in this thesis does not breach copyright regulations.

Abrar Ahmad Chughtai (Candidate): 

RATIONALE OF THE STUDY

Review of policies and guidelines showed that most policy documents did not mention the use of cloth masks (Chapter 2). However, the use of cloth masks was reported to be a common practice in low/middle income countries. Some HCWs prefer to use cloth masks due to comfort and availability in the hospitals. However, there is a lack of evidence around the efficacy of cloth masks and very few high quality studies were conducted around the efficacy and use of cloth masks in the health care setting (Chapter 1). In this chapter, I examined the available evidence around the efficacy and use of cloth masks in health care settings.

Research question:

What is the evidence around the efficacy of cloth masks in health care settings?

CONTRIBUTION TO THE THESIS

This study showed that cloth masks have been used historically not only for source control but also for respiratory protection. However, there is a lack of information around the efficacy of cloth masks in health care settings. I discussed various options regarding the use of cloth masks in low resource countries and proposed various methods to improve the effectiveness of cloth masks.

ABSTRACT

Cloth masks are commonly used in low and middle income countries. It is generally believed that the primary purpose of cloth masks is to prevent spread of infections from the wearer. However, historical evidence shows that they have been used to protect health care workers (HCWs) from respiratory infections. Currently there is a lack of evidence on the efficacy of cloth masks. In this paper, we examined the evidence around the efficacy of cloth masks and discuss the use of cloth masks as a mode of HCW protection from infections. We also reviewed the various approaches implemented to try and improve the effectiveness of cloth masks; for example; type of fabric, mask design and face fit.

Our results highlight that there is currently no published research on the efficacy of cloth masks. The few available studies on cloth masks are either descriptive or in-vitro. Studies show that some fabrics may provide better protection than others, and that in-vitro filtration capacity improves with increasing fineness of fabric and number of layers. The presence of moisture, distance travelled by the droplets and the mask design were identified as other important factors related to in-vitro filtration efficacy. Cloth masks may provide some protection and reduce exposure to respiratory aerosols, but this is unproven in the absence of a RCT. Given that cloth masks are widely used around the world and are not adequately addressed in infection control guidelines, research is required to test the clinical efficacy of cloth masks. Other future research questions should include filtration efficacy, length of use, methods of decontamination and fit testing. The use of cloth masks should be addressed in policy documents to inform best practice in low and middle income countries.

BACKGROUND

The use of personal protective equipment (PPE) is recommended for the prevention of infections in the health care setting (1-5). Masks and respirators are the most common products referred to in guidelines to prevent the spread of pathogens through the respiratory droplet and airborne (aerosol) routes (6-22). The main difference between the two products is their intended use. The described purposes of face masks are to prevent the spread of infections from the wearer and to protect the wearer from splashes or sprays of blood or body fluids, whereas respirators are used to protect the wearer from others with confirmed or possible respiratory infections (1, 11, 23-25). However, in low resource settings, the provision of single-use surgical masks and respirators may not be feasible. Instead, various types of cloth masks (i.e. cotton/woven or gauze) are also widely utilized in various health care settings in resource-poor countries. In countries such as China and Vietnam, where the historical risk from emerging infections is high (26, 27), use of cloth masks by health care workers (HCWs) is widespread (28-30). Currently, there is a lack of sufficient information to either support or refute the effectiveness of cloth masks, in preventing transmission of infections (25). In this article, we examine the historical and present role of cloth masks in the health care setting and the evidence regarding the effectiveness of the product. In this setting, we refer to cloth masks as 'reusable masks made of cloth or any other fabric, including cotton, gauze, silk or muslin'.

USE OF CLOTH MASKS IN THE HOSPITAL SETTING

The first evidence of mask use can be traced to the late 19th century, when gauze masks were used by patients to prevent the spread of infection (31, 32). In 1905, Hamilton proved the presence of streptococci in sputum droplets and suggested that HCWs use masks to prevent spread of streptococcal infection in operating theatres (33). It is generally believed that masks were primarily designed to prevent spread of infections from the wearer, i.e. from both patients and HCWs, which is referred to as "source control" (34). However, the literature shows that masks were also used to protect HCWs from acquiring respiratory infections in early 20th century.

The Institute for Infectious Diseases in Chicago was the first to recommend that masks be used to protect HCWs from respiratory infection. HCWs in Durand Hospital, Chicago used double layered gauze masks from 1913 to 1916 (35), which were later changed to triple layered masks in 1919 (31). Low rates of respiratory infections amongst HCWs were observed after using these masks. Cloth masks were also thought to be effective for preventing secondary transmission of diphtheria and scarlet fever in the patients and HCWs of an Army camp in 1918 (36). Cotton masks made up of various numbers of layers were used by HCWs and the public during the 1918 Spanish influenza pandemic, however the number of influenza cases continued to rise despite regular mask use (37-40). Low perceived effectiveness of the masks used during that pandemic was attributed to the poor quality of masks and inappropriate use of masks (40). In comparison, the rate of infection was very low amongst HCWs who used masks made of a half-inch thick cotton pad enclosed by two layers gauze, during the Manchurian plague epidemic in 1920–1921 (41). HCWs were also documented to have used pillow slips and celluloid to make masks during the 1924 epidemic of plague in Los Angeles (42). The use of cloth and gauze masks continued during the 1930's and 40's by nurses for the prevention of TB (43-45). These masks continued to be recommended for use during the 1950s and 1960s, even though a few disposable masks had been introduced into the market by then (46).

The extent to which cloth masks are currently being used in low and middle-income countries is impossible to gauge, as the data currently available are limited. However, based on anecdotal information, it is believed that the practice is widespread in Asia, for example in China (29) and Vietnam (28, 30). Furthermore, there were reports that cotton masks were used by HCWs during the SARS outbreak in China (29, 47). In the initial phase of the SARS outbreak in Vietnam, approximately 70% of HCWs wore cloth or surgical masks, however, after the first week there was 100% N95 respirator use (48). However, in our experience conducting clinical research, a wide range of unproven practices occur in many of these settings, including double-masking, extended or re-use of masks and washing of masks using various techniques. There is little evidence of cloth mask use in high income countries, however some researchers have recommended the use of cloth

masks for HCWs who have adverse effects when using respirators for long periods (49, 50). In addition, some regional pandemic influenza plans discuss the use of cloth masks in certain situations. For example; in California, the Sonoma County Department of Health Services developed a plan for pandemic influenza and recommended cotton masks in the event of a shortage of N95 respirators and surgical masks (51).

Table 7.1: Studies on cloth masks

Authors/ year of study	Type of study	Focus of the study (Protect wearer or protect spread to others)	Methodology	Type of material tested	Main findings
Weaver 1918 (35)	Observational	Protect HCWs from infections	Rates of diphtheria and scarlet fever were compared in the HCWs in two periods; i.e. before and after use of masks	Two layered gauze masks	Low rates of diphtheria and scarlet fever observed in HCWs after using masks
Capps 1918 (36)	Observational	Prevent spread of infection from wearer and protect wearer from infections	Facemasks were used by HCWs and patients in Camp Grant and upon success of the experiment, mask use was started in all medical wards	Cloth masks	The secondary transmission of scarlet fever and measles was reduced in the wards by using masks
Haller 1918 (59)	Laboratory	Prevent spread of infection from wearer	Patients coughed on petri dishes covered by various gauze masks. Then experiment was repeated with double masks, i.e. one on petri dish and one on patient's mouth. Numbers of colonies were counted.	Gauze masks of various types	The number of colonies depends on the type of gauze and number of layers
Doust 1918 (57)	Laboratory	Prevent spread of infection from wearer	Agar pates were placed in front of study subjects, while they spoke, talked and coughed with and without gauze masks. *Bacillus prodigiosus* was used to test various masks.	Two to ten layers of masks made from coarse gauze, medium gauze, and butter cloth	Three layer butter cloth masks, made of fine gauze, were found to be more effective in preventing spread of infection
Leete 1919 (58)	Laboratory	Prevent spread of infection from wearer	An emulsion of staphylococci was sprayed on the petri dishes covered by gauze of various types and layers	Dry and wet ordinary surgical gauzes, fine muslin	6 to 8 layers of fine muslin provided better protection than gauze masks. Dry masks are better than wet masks.
Weaver 1919 (31)	Laboratory	Prevent spread of infection from wearer	*Bacillus prodigiosus* (in NaCl solution) was sprayed onto a petri dish by a hand atomizer through an opening in cardboard. Various types of gauze were placed onto the opening. The experiment was then repeated with a patient with respiratory infection. The number of colonies in the petri dish (containing nutrient and blood agar) was measured.	Gauze masks of various types and numbers of layers were used	The number of colonies in the petri dishes was decreased by increasing the distance of the spray from the opening, increasing fineness and number of layers of cloth
Kellogg 1920 (40)	Observational and Laboratory	Prevent spread of infection from wearer and protect wearer from infections	Report of State Health Officials on the use of masks in California, during the influenza outbreak in 1919, followed by a series of laboratory tests	Gauze masks	Certain types of masks may be effective, (depending on type of cloth and number of layers), however use should not be compulsory. Leakage around the face increased when thin layer of gauze used.

Walker 1930 (74)	Observations and Laboratory	Prevent spread of infection from wearer	Survey in 100 hospitals; 60 hospitals responded and 42 sent mask samples. Masks were worn by student volunteers who were carriers of *Streptococcus* and petri dishes were placed in front of them. The numbers of colonies were counted at the end.	Various types of masks tested, including a 10 inch gauze mask of two layers, with 6 inch rubber in between	Of 42 masks, only 7 masks were of good quality. None of them was germ-proof in testing. Gauze mask with rubber in the centre was considered germ proof.
Blatt 1933 (61)	Laboratory / observational	Prevent spread of infection from wearer and protect wearer from infections	A dust-proof tunnel was constructed. Two nurses with respiratory infection were given various masks and asked to cough in the champers. Petri dishes were placed in the champers at various distances and colonies were counted later. New mask use was observed in nurses.	Various types of commonly used masked and a newly made cellophane gauze mask	Simple 6 layer gauze masks were not effective. Newly made cellophane gauze masks were effective and comfortable to wear.
Paine 1935 (62)	Laboratory	Prevent spread of infection from wearer	Tested the penetration of high momentum droplets through various fibres. An apparatus, similar to the shape of face was used, with three holes representing the nares and mouth. Atomizer charged with a broth culture of *M. lysodeikticus* was sprayed. The colonies were counted on nutrient agar.	Silk, surgical gauze and dental gauze	Two layers of silk, eight double layers of surgical gauze and four layers of dental gauze are effective in reducing droplet penetration. The design of mask is important.
McKhann 1938 (60)	Laboratory	Prevent spread of infection from wearer	Bacteria were sprayed on petri dishes covered by the various masks. The numbers of colonies were counted.	Gauze mask, impervious mask, paper masks and a new type of filter mask (cotton layers between the gauzes)	New type of filter masks were most effective. Paper masks were not effective as they become wet very quickly.
McNett 1949 (44)	Observation	Protect wearer from infections	Developed series of masks and checked their efficacy by various means, including rate of infection among the nurses.	Various types and layers of cloth masks	50% reduction in the prevalence of TB was observed in the nurses after using 6 layer cloth masks
Lurie 1949 (43, 69)	Animal testing in laboratory	Protect wearer from infections	Bovine TB bacilli were nebulized into a chamber and faces of rabbits were exposed to the TB bacillus. Masked and unmasked rabbits inhaled in the chamber and tuberculin tests were performed to see the rate of infection.	3 to 6 layer of gauze masks	4 to 6 layer gauze masks effectively filter 90 to 95 of the bacillus. Wearing masks was recommended.
Shooter 1959 (52)	Laboratory	Prevent spread of infection from wearer	Evaluated three types of masks to prevent the spread of staphylococci from a volunteer's month. A chamber was made with help of a table and canopy. Volunteers used three types of masks and the numbers of colonies were	Four layer cotton mask, double layer woven cambric with a piece of paper in between, a paper	All masks were found effective in preventing spread of staphylococci infection

			counted on the blood agar in the petri dishes placed in the chamber.	mask with outer and inner layer of paper with cellulose wadding between	
Greene and Vesley 1962 (53)	Laboratory	Prevent spread of infection from wearer	Used a specially designed chamber to collect air samples. Study subject breathed into the chamber with and without mask and the numbers of oral bacteria on blood agar were counted.	Masks made of two layers of fine muslin	Masks were effective mainly against large particles, i.e. greater than 4 um
Quesnel 1975 (46)	Laboratory	Prevent spread of infection from wearer	Tested five masks of various types and design. Testing chamber used to collect contaminated particles through the masks and around the masks.	Four layer cotton masks, various types of surgical masks made of polyester and rayon fibres	All masks were effective against large particles; however three of them were more effective against small particles. Results using well-designed cotton masks are comparable to those using synthetic fibre masks.
Dato 2006 (54)	Laboratory	Prevent spread of infection from wearer	Cloth mask was used on the panel faces and challenge agent was measured inside and outside the mask with Portacount Plus Respirator fit tester with N95 Companion	Cotton (heavyweight T-shirts) of various layers	Handmade masks can provide good fit and reasonable protection
Sande 2008 (55)	Laboratory	Protect wearer from infections	Healthy volunteers wore respirators and various masks. Protection factor was measured with fixing receptors inside and outside the masks to count free particles. Portacount was used to count the particles.	Compared respirator, surgical mask and homemade cloth mask	All masks provide some protection, however respirators provide maximum protection, followed by surgical masks and then homemade cloth masks
Rengasamy and colleagues 2010 (56)	Laboratory	Protect wearer from infections	Tested the filtration performance of various types of cloth masks against the polydisperse and monodisperse aerosol particle in the 20–1000 nm range. TSI 8130 Automated Filter Tester (TSI 8130) was used for test.	Various types of fabrics were tested, including sweatshirts, T-shirts, towels, scarves, and cloth masks	The respiratory protection is minimal with cloth masks and certain types of cloth fabric may impart more protective value than others.

EFFECTIVENESS OF CLOTH MASKS

The first study on cloth masks was published by Weaver in 1918 (35). He examined the rate of diphtheria and scarlet fever among the nurses before and after the use of two layered gauze masks. He reported a significant reduction in the incidence of diphtheria (23.5% to 5.2%) and scarlet fever (8% to 0%) amongst the nurses. In a second study, he tested masks made with various numbers of layers in a controlled environment. There was an improvement in the effectiveness of gauze masks associated with increasing fineness of the cloth and the number of layers (31). In 1959, Shooter and colleagues evaluated three types of masks to prevent the spread of staphylococci from the wearer. They compared a four layer cotton mask, with a mask made from two layers of woven cambric with a piece of paper in between and a paper mask surrounded by cellulose wadding. All three masks were found effective in preventing spread of staphylococcal infection (52). A couple of years later, Greene and Vesley evaluated a two layer gauze mask and found that it was effective in blocking particles greater than 4 um (99.6%) and less than 4 um (96.7%) (53). Lastly in 1975, Quesnel assessed various types of surgical and cotton masks and concluded that well designed cotton masks may be effective in preventing infection (46).

During the middle of the 20th century, the focus of research around mask use was to protect HCWs from tuberculosis (TB). McNett developed a series of masks and checked their effectiveness by estimating the rate of infection among the nurses. A 50% reduction in the prevalence of TB was observed amongst nurses who used the 6 layer cloth mask (44). Cloth masks were also found effective in protecting rabbits against the inhalation of tubercle bacilli (43). Since the development of surgical masks and respirators, very little research has been conducted on cloth masks. To our knowledge, only three studies were done on cloth masks during the 21st century, all in a laboratory setting. Dato and colleagues tested a handmade mask, made from cotton T-shirt material, for fit and filtration. After introducing the challenge aerosol, substantial protection and good fit were reported (54). In the 2nd study, Sandy and colleagues studied respirators, surgical and cloth masks and concluded that all three products provide respiratory protection to a

degree, with respirators providing the maximum protection and homemade cloth masks the minimum (55). Lastly, Rengasamy and colleagues tested the filtration performance of various types of cloth masks and concluded that respiratory protection is minimal with cloth masks but that certain types of cloth fabric may have more protective value than others (56).

Three factors were highlighted in these studies in regards to the filtration capacity of a cloth mask: 1) closeness of the gauze/cloth threads; 2) number of gauze/cloth layers and 3) type of gauze/cloth. Generally, the filtration capacity improved when the number of threads increased in the gauze and the mesh become finer, compared to course gauze with lower thread counts (31, 40, 57). Similarly, the number of layers was found to be directly proportional to the filtration capacity in most of the laboratory studies. In these studies, the filtration effectiveness significantly improved with increasing the number of layers in the mask (31, 40, 58, 59). Certain types of cloth provides better protection than others; e.g. fine muslin (loosely-woven cotton fabric) was better than gauze (58), gauze padded with cotton was better than simple gauze or paper masks (60) and towels were more effective than other fabrics (56). Cloths masks were generally found to be effective against large particles (>4 um) (53), however some there is some evidence that they are effective against small particles as well (43). Presence of moisture, distance travelled by the droplets and the design of mask were some other factors affecting filtration capacity. In summary, the filtration capacity of wet masks has been reported as being lower than dry masks (58, 60). The distance travelled by the droplets is associated with the filtration capacity and filtration capacity is generally decreased by decreasing distance (31, 61). Finally, the design of a mask is also important and some designs are more effective than others, particularly those with a tight seal around the face (40, 54, 61, 62).

There are many limitations in the available research around cloth masks. Firstly, most of the studies were conducted in first half of the 20th century. Since the development of disposable surgical masks in the 1960's, very few studies have been conducted on cloth masks, and to date there have been no randomized, controlled trials (RCTs) of cloth

masks. Recently published RCTs and other studies have focused only on surgical masks and respirators (21, 63-67) . Secondly, most of the studies on the use of these products have been in laboratory settings, using bio-aerosols and manikins (46, 52, 53, 62, 68). Thirdly, extended use and re-use of cloth masks have not been discussed in much detail in the literature. Extended use refers to 'using a mask or respirator by the same wearer for a prolonged time'. Staff may continue to use the same mask over a period of time without removing it or may don/doff the mask between patients. A recent survey in Vietnam revealed that HCWs use masks for varied lengths of time (30). Reuse after decontamination refers to the mask being reused over multiple days/weeks/months by either the same or different HCW. Cloth masks are typically washed or decontaminated between uses. Various decontamination methods have been documented, for example; autoclave, isopropyl alcohol, bleach, hydrogen peroxide, microwave, soap and water, ultraviolet radiation and dry heat (25). While the material of cloth masks is unlikely to degrade with standard means of disinfection (e.g., chemicals, heat, and radiation), unlike other types of disposable facemasks or respirators, there is currently little evidence about the effectiveness of these decontamination methods.

As a result of these laboratory studies, the use of cloth masks was recommended for HCWs (31, 35), particularly during epidemics and pandemics in the early 19th century (37-42). Therefore, whilst these studies were only conducted to examine the spread of infections from the wearer, the same studies were also used to justify the use of masks in preventing HCW infection (35, 43, 69). During the 1918 influenza pandemic, authorities quoted the same studies in order to implement compulsory use of mask in hospitals and public places (37, 38).

POLICIES AND GUIDELINES AROUND THE USE OF CLOTH MASKS IN THE HEALTH CARE SETTING

References to or recommendations around the use cloth masks are currently not made in any publically available guidelines regarding the use of PPE for routine care to protect against respiratory virus transmission. A review of publically available pandemic influenza

policy documents reveals that none of the guidelines mention the use of cloth masks (70). However, the use of cloth masks has been discussed for other infectious diseases. In cases of non-availability of surgical masks, the CDC recommends using cotton masks made from four or five layers of cotton cloth for infection control of viral haemorrhagic fevers in the African health care setting (71). The WHO discouraged mask use in the community setting during influenza A (H1N1) outbreaks due to lack of evidence, however, the option of use and reuse of various types of cloth masks is discussed. In the case of cotton masks, the WHO advises washing cloth masks with household detergent after use (72).

THE USE OF CLOTH MASKS DURING AN EXTENDED OUTBREAK OR PANDEMIC

According to a CDC estimate, approximately 1.5 billion masks and 90 million respirators would be needed by the health care sector and around 1.1 billion masks would be needed by the public for a six week influenza pandemic (25). For most low income countries, it is highly unlikely that they would be able to provide disposable masks, let alone respirators for that length of time and may have to ration the use of these products. During an extended outbreak or influenza pandemic, the use of cloth masks may be the only option available in low resource settings. In a survey conducted in Japan during the SARS outbreak, around 40% of HCWs agreed that gauze masks may be used to protect from SARS (73). Recently, the high demand for masks and the potential reliance on cloth masks during an influenza pandemic, was acknowledged by the US Institute of Medicine (IOM) when preparing their report on the reusability of facemasks. The committee members did not advise against the use of cloth masks, however they recommended that further research be undertaken on the use of cloth masks, including commonly used fabrics like T-shirts, handkerchiefs and scarves (25). One of the issues is that the quality and nature of cloth masks used around the world are varied and not subject to any regulation. Currently, only N95 respirators are subject to regulation around filtration capacity. It is currently not clear whether the wide range of cloth masks or improvised masks can meet the standards set by regulatory bodies (25). Interestingly, it should be noted that surgical masks are similarly not subject to any regulation, and face the same issue. There is currently a

concern that cloth mask use may give users a false sense of protection in the absence of proven efficacy that will encourage risk taking and/or decrease attention to other hygiene measures (25, 56).

CONCLUSION

Although cloth masks are commonly used in low/middle income countries, there is minimal policy acknowledgment about the need for cloth masks, and a lack of evidence on their efficacy and use. Cloth masks are generally not mentioned in any policies on the use of PPE during an influenza pandemic. The lack of recommendations for respiratory protection may be due to a lack of evidence on their efficacy. Despite the lack of evidence and the little attention paid to cloth masks in guidelines and policies, they continue to be widely used around the world, particularly in resource-poor countries. In many settings, the high cost of masks and respirators (around $0.14USD per surgical mask and $0.63USD per N95 respirator for products manufactured by a leading company) is probably one of the main factors inhibiting the regular use of these products. More concerning is the fact that cloth masks are widely used in countries that have been historically important for the emergence of new infections, such as China and Vietnam. There is an urgent need a RCT to quantify the efficacy of cloth masks, and also to study the various associated practices such as re-use and decontamination techniques globally. Future research questions could focus on clinical efficacy, filtration efficacy, length of use, methods of decontamination and fit testing. The use of cloth masks should be addressed in policy documents to inform current practice in low and middle income countries.

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CHAPTER 8

DISCUSSION AND RECOMMENDATIONS

DISCUSSION

In this chapter, I will discuss the implications for the results for each of the chapters and will explain how different studies are inter-related and answer the research questions. Recommendations have been developed based on my research to inform policy and to guide practices around the use of facemasks and respirators in the health care setting. Finally, I will discuss the strengths and limitations of this work in the broader context. The strengths and limitations of individual studies have already been discussed as part of the previous chapters.

Recommendations must be based on the available evidence, however in the context of the limitations often placed on governments/health systems in low resource countries. Therefore various policy options are explored for low resource settings that I consider more practical and appropriate for resource poor countries. The recommendations in this thesis are based on:

1. A review of published literature and other available evidence (1, 2) (Chapters 1 and 7)
2. Analysis of policies and guidelines of selected health organisations and countries (3, 4) (Chapters 2 and 3)
3. Analysis of existing practices and prevailing situations in low and middle income countries (5, 6) (Chapters 4 and 5)
4. Analysis of organisational and individual factors (5-7) (Chapters 4, 5 and 6)

Although this thesis focuses on low/middle income countries, the recommendations may be applicable to high income countries in certain situations. The consumption of PPE increases significantly during outbreaks/pandemics, and non-standardised practices can even be observed in high income countries (8, 9). For example, staff may resort to using non-recommended types of masks or extending the use of the product or re-using the product during high demand periods. During the 2009 influenza H1N1 pandemic, shortages of respirators were reported in some US hospitals, therefore staff resorted to using medical masks (8, 9). In addition, all sizes of respirators were not available so staff had to use a larger size respirator (8). Shortages of products have also

been reported in other countries. For example a Japanese study examined the preparedness of primary health care facilities during the H1N1 pandemic. The results showed that while 84.5% of facilities had stocks of surgical masks, only 45.4% had stocks of N95 respirators (10). Finally, HCWs in high income countries may not be aware of policies and guidelines regarding the use of facemasks and respirators as reported in a recent Australian study (11). Therefore, recommendations presented in this thesis may be applicable to all similar situations.

Table 8.1: Summary of the key findings of the studies

Chapter title	Research question addressed	Main findings
Availability, consistency and evidence-base of policies and guidelines on the use of masks and respirators to protect hospital health care workers: a global analysis. (Chapter 2)	• Do health organizations and countries have varying policies and guidelines around the use of facemasks and respirators?	• Health organizations and countries have different policies and guidelines around the use of facemasks/respirators. • Type of product recommended and terminologies used to describe product/setting of use were the main inconsistencies observed in policies and guidelines. • Most of the guidelines did not discuss policies on re-use and extended use of facemasks. • There was a lack of guidance on the use of cloth masks, despite the recognised widespread use in many low and middle-income countries.
Examining the policies and guidelines around the use of masks and respirators by healthcare workers in China, Pakistan and Vietnam (Chapter 3)	• Do health organizations and countries have varying policies and guidelines around the use of facemasks and respirators?	• In Pakistan and China, the guidelines were developed to be in line with the recommendations from the WHO and the CDC, while in the Vietnamese guidelines, the recommendations correspond with the WHO only. • While the guidelines from both Pakistan and China discuss at length the use of masks/respirators, only the Chinese policy includes information regarding the regulation and certification processes that should be implemented for respirators. • Across the three countries, there were some inconsistencies in regards to the types of products (i.e. masks vs. respirators) recommended for influenza, SARS and TB. • The reuse of masks after decontamination is not recommended in any guideline.

Practices around the use of facemasks and respirators amongst hospital healthcare workers in three diverse populations (Chapter 4)	• Do hospitals follow national infection control policies and guidelines for the use and re-use of facemasks? • What types of facemask are being used at the hospitals level?	• The practices being reported in hospitals are not in line with the national infection control guidelines. • Various types of facemasks and respirators are being used in hospitals. These products were found to not only differ in the type, but also vary in shape, numbers of layers and filtration efficacy. • Certification and regulation processes are not currently implemented. • Facemasks and respirators are being used for various lengths of time in three countries. • Facemasks and respirators were re-used in all countries during outbreaks/ pandemics.
Current practices and barriers to the use of facemasks among hospital based healthcare workers in Vietnam (Chapter 5)	• What are the practices and perceptions of hospital-based health care workers regarding the use of facemasks and respirators?	• Facemasks and respirators were considered to be an effective approach for preventing respiratory infections. • "Availability" of facemasks in the hospitals was the strongest theme to emerge from the discussions. Participants highlighted that it is not unusual for some facemask types to be unavailable during non-emergency periods and that shortages of facemasks also occur. • Medical and cloth masks are used in most Vietnamese hospitals, and the use of respirators was reported to not be very common. • Participants highlighted that the use of facemasks and respirators is not continuous; rather it is limited to selected situations, locations and patients. • The re-use of facemasks and respirators was suggested to be a common practice, however, there were mixed views regarding the re-use. Some participants considered the practice to be safe, while others thought the practice placed them at risk of contracting an infection.

Factors affecting compliance of health care workers with the use of facemasks (Chapter 6)	• Which factors are associated with the compliance and use of facemasks among hospital-based health care workers?	• The reported level of compliance with the use of facemasks decreased over the study period. • The presence of adverse events, contact with febrile respiratory illness patients and performing aerosol generating procedures were significant predictors of compliance. • General discomfort and breathing problems were the most common reported adverse events. Compliance was significantly lower among participants who reported discomfort and breathing problems. • Being compliant with the facemask use was not associated with clinical respiratory illness (CRI), influenza like illness (ILI) and laboratory-confirmed viral respiratory infection.
Use of cloth masks in the practice of infection control – evidence and policy gaps. International Journal of Infection Control. (Chapter 7)	• What is the evidence around the efficacy of cloth masks in health care settings?	• Facemasks are generally used to prevent the spread of infections from the wearer; however, historical evidence shows that cloth masks have been used for the purpose of protecting HCWs from respiratory infections. • Most of the studies on cloth masks were in-vivo, conducted during the first half of the 20th century and rarely discussed issues around extended use and re-use. • The available evidence suggests that cloth masks may provide some protection and reduce exposure to respiratory aerosols. Cloths masks were generally found to be effective against large particles. • The following factors have been found to impact on the filtration capacity of a cloth mask: closeness of the gauze/cloth threads, number of gauze/ cloth layers, type of gauze/cloth, mask design and presence of moisture.

8.1 INCONSISTENCIES AND GAPS IN THE POLICIES AND GUIDELINES

Two studies were conducted at the health department level that aimed to examine the policies and guidelines of health organisations and countries and to describe areas of consistency and inconsistency between guidelines, as well as gaps (3, 4) (Chapters 2 & 3). These studies highlighted inconsistencies in the policies and guidelines around the use of facemasks/respirators in health care settings. It could be hypothesised that due to these variations in the policies/recommendations, the hospitals and staff may be implementing practices that are not the best or are not evidence based (6). The main reason for this is a lack of level 1 evidence around the efficacy of facemasks and respirators, with only four clinical trials based in the health care setting to date. Furthermore, most HCWs in low resource countries do not have access to a wide range of information, therefore using a different terminology when referring to facemasks/respirators and the high/low risk situations they should be used in, may also result in discrepancies in selecting various types of products (3).

Health departments in low resource countries may look towards the WHO or the CDC policies for guidance when setting their own polices (4), however the recommendations of these organisations also vary, and may depend upon availability of resources (3). As a result of not having clear guidelines, in-country health departments and hospitals may be influenced by other factors such as cost/availability when deciding which products are to be supplied to staff members. Although low/middle income countries are more likely to face these problems, hospitals in high income countries may not be immune to these issues. A survey in the US showed that hospitals were selecting various types of respiratory protection (N95 respirators vs. medical masks) for their staff. The authors felt this was associated with the conflicting guidance coming from the WHO and the CDC, and a lack of evidence around the efficacy of N95 respirators (8).

Although most of the guidelines have mentioned the importance of regulations, training and fit testing for respirator use, very few of them provide any actual details on these

elements (3). As long as clear and consistent guidance is not being given, HCWs may continue with non-standard practices, such as extended use, re-use and the use of cloth masks, (3, 4). Non-compliance with standardised practices and using non-standard practices may put HCWs at risk of acquiring various infections.

Recommendation 1: Policy documents need to be reviewed in the light of terminology and completeness

Policy documents must address critical areas such as regulations, re-use/extended use and the use of cloth masks. Health organizations and countries should jointly evaluate the available evidence around the use/re-use of facemasks and use of cloth masks to make such policy documents. Policies should be based on available evidence and best practices, however the situation in low resource countries must also be considered and various options should be explored to make policies practicable, so that they may be implemented. The definition of 'high risk' situations must be standardized across the guidelines. In addition, when referring to 'respirators' policies/guidelines must include the following information: series (e.g. "N" or "P") and filtration capacity (e.g. "95% or 99%).

Policy documents should discuss benefits and risks of extended use and re-use of facemasks and respirators. If used for extended period, facemasks/respirators should be stored in a safe place and should be used by same wearer (12). Methods of decontamination should also be discussed in the policy documents. Currently, cloth masks are being re-used in low/middle income countries, and are undergoing various 'decontamination' techniques such as boiling and washing with soap and water (6, 13). It is crucial to determine the best system of decontamination that may be implemented in low resource settings. For example, the WHO has worked out systems of making hand wash solution that take into account scarcity of water or ingredients and also provide instructions on how to make alcohol based hand rub from locally available ingredients (14). As tap water may not be easily available in remote areas of low resource countries and may be a source of nosocomial infections, other decontamination methods should be

tested to clean facemasks. In regards to reusable respirators, the manufacturer's guidelines should be followed for decontamination.

8.2 RECOMMENDING VARIOUS TYPES OF RESPIRATORY PROTECTION

Health organisations and countries recommend different types of facemasks and respirators due a paucity of high quality studies and a lack of efficacy data. The ongoing threat from various avian influenza strains in Asia and the 2009 influenza pandemic drove a new round of research on the topic of masks/respirators that included a number of large RCTs (15-28). Three clinical trials undertaken in the health care setting compared the efficacy of medical masks and respirators in the prevention of respiratory transmission (16-18). Two relatively recent large clinical trials in China showed superiority of N95 respirators over medical masks against clinical infection, however the difference was not statistically significant for laboratory confirmed influenza (17, 18). There was no difference between the outcomes in the third trial, which compared the targeted use of either N95 respirators or medical masks (16). The selection between mask and respirator for SARS is also controversial and while some studies favour respirator use (29-32), others have failed to demonstrate the superiority of respirators over medical masks (33-35). Most observational studies are also inconclusive, however laboratory studies show high protective value of N95 respirators compared to medical masks (36-38). Although the use of respirators is highly recommended for tuberculosis (TB), their efficacy against TB is yet to be proven, with no RCTs conducted to date. Although respirators are generally considered superior to medical masks against TB (39-42), improvement in TB control was mainly attributed to administrative and environmental controls, rather than replacing masks with respirators (43).

The risk of infection transmission increases during AGPs and other high risk situations, warranting superior respiratory protection (44). As discussed in Chapter 1, respiratory aerosols are generated during AGPs resulting in "aerosol transmission", which includes, but is different from "airborne transmission" (45). For example, influenza and SARS are

thought to primarily be spread though the droplet route, however “aerosol transmission” may occur during AGPs (45). A respirator is sealed tightly around the face and provides more protection compared to medical masks against “aerosol transmission” (16-18, 44). In an RCT, the majority of laboratory confirmed infections were due to respiratory syncytial virus and influenza, neither of which are thought to be predominantly airborne, yet N95 respirators were superior to surgical masks in protecting HCWs (18). This shows that respirators may provide better protection against influenza, particularly during AGPs. Most laboratory studies also favour the use of respirators in high risk situations due to high filtration efficacy and fit factor (36).

Recommendation 2: Selection between facemasks and respirators

Selection of facemasks/respirators primarily depends on mode of transmission of the disease to be prevented, however organisational (availability, cost, OHS obligations) and individual (risk perception, adverse events, pre-existing medical illness) factors should also be considered (46). Droplet particles are larger than 5 μm in size and they do not suspend in the air and can infect people within 1-2 meter of the index case. Influenza primarily transmits through the droplet route and medical masks are generally recommended (3, 47, 48). Routine use of respirators is not recommended for influenza due to a lack of efficacy data and cost implications (49). On the other hand, airborne transmission occurs through particles less than 5 μm, which suspend in the air and can be transmitted over long distances, for example TB. A properly fitted N95 (or higher) respirator are generally recommended and used to protect HCWs from TB (3, 47, 48). A respirator should also be preferred during AGPs and other high risk situations.

However currently there is debate around the primary modes of various organisms and most pathogens are through to be transmitted through more than one mode (45). In that case, selection of masks/respirators should be based on the risk of the pathogen to HCWs and superior respiratory protections should be considered. Generally facemasks do not offer effective protection against the inhalation of infectious aerosols. Selecting

respiratory protection from pathogens that can be aerosolised is more important than whether a pathogen is currently classified as either droplet or airborne transmitted. For example, seasonal influenza does not pose as much risk to HCWs as does a pandemic influenza strain that causes severe illness in HCWs, particularly before a vaccine in available. A respirator should be preferred in these situations.

Recommendation 3: If there is uncertainty around the transmission mode and high morbidity/mortality, superior respiratory protection should be preferred

N95 or higher quality respirators should be the preference during outbreaks and pandemics due to the uncertainty around the transmission mode of the pathogen and the potential for increased risk of morbidity and mortality (3, 47, 50, 51). Respirators should also be used for pathogens that cause high morbidity/mortality in HCWs and for which there are no prevention or treatment options is important. Transmission could be high in HCWs who care for patients that present in hospitals with atypical symptoms (52). Current PPE policies are based on out-dated transmission studies, which showed that infections are transmitted by mutually exclusive contact, droplet or airborne routes (45, 53-55). The recent evidence however suggests that most pathogens transmit through multiple routes, and that aerosols may be generated without high risk procedures (45, 56). Therefore, current dogmatic paradigms about pathogens and their transmission is much debated, particularly when the disease in question has a high case-fatality rate and no proven pharmaceutical interventions (46). Finally, there is a complex relationship between bacteria and viruses in the respiratory tract, and dual infections appear to be common in HCWs, with multi-mode transmission (57). Using an N95 respirator reduces these risks and the seal achieved by a respirator is an additional benefit over and above superior filtration.

8.3 UNAVAILABILITY OF FACEMASKS AND RESPIRATORS AT FACILITY LEVEL

This study showed that facemasks and respirators may not be available at the facility level in low resource countries and HCWs have to reply on alternative options or have to purchase these devices themselves (5, 6). The situation may worsen during outbreaks and pandemics when the use of PPE increases significantly (58-61). The use of facemasks and respirators was significantly increased during the SARS outbreak in 2002-03 and the H1N1 pandemic in 2009 (60, 62-64). Simulation studies also showed that the demand for respirators and other PPE would be expected to increase significantly during outbreaks and pandemics (65, 66). If health departments do not provide clear guidance on the use of facemasks and respirators in these situations, HCWs may follow non-standardised practices.

Recommendation 4: Operational guidelines should mention alternative options in the case of unavailability of certain types of facemasks/respirators

The guidelines for low resource countries should be based on current evidence and best practices, even if it's unaffordable (46). Then less effective and less costly alternatives can be considered along with their disadvantages and health organisations and countries may recommend alternate options in case there is a shortage of facemasks or respirators or an increase in demand. If respirators are unavailable, facemasks should be used to protect from splashes and sprays of blood and body fluids. Cloth masks should only be used as the last option and paper masks should not be used as they become wet easily. Respirators should be available in different sizes so that the appropriate size may be used by HCWs. In case of non-availability of proper size, another respirator may be used, though it may not protect against airborne infection and may increase risk to HCW. Another option is to prioritise the use of respirators for frontline HCWs and other high risk situations such as performing AGPs and working in high risk wards (67, 68).

PPE should be stockpiled in sufficient quantity for pandemics, however most low resource countries may not be able to do so. Moreover, there is no standard method to estimate

the stock level needed to ensure availability during pandemics. It has been estimated that when considering both confirmed and suspected cases, approximately 10 respirators and 10 masks per patient per day or on average 200 respirators and 155 medical masks per confirmed or suspected hospitalised case would be required (60). In addition to necessary quantities, guidelines should be developed on storage as respirators have a stated shelf life (e.g. three years for FFP3), while there is no stated shelf life for medical masks (66). However, there is limit data around the shelf life of respirators stored under optimal conditions and limit evidence about their "expire" in the traditional sense of the word.

8.4 POLICIES ARE NOT TRANSLATED INTO CLINICAL PRACTICES

The findings from the studies reported in Chapters 4, 5 and 6 highlight that the recommendations are currently not being translated into best practice (5, 7). In the settings studied, non-compliance with national policies is probably due to limited resources to purchase facemasks and respirators and a lack of expertise to implement comprehensive respiratory protection programs (6). Facemasks and/or respirators may not be available in sufficient quantity at the facility level in low resource countries, which means that HCWs have to rely on alternate options (6). In some cases, HCWs have to purchase these devices themselves and are likely to select low cost products that compromise quality and efficiency (6). The risk of infections increases if HCWs are not adequately protected.

Recommendation 5: A facilitative environment should be created in the health facility to translate policies into clinical practices

Previous studies have shown that organisational factors are more important than those of individuals with regards to protection behaviours (59, 69, 70). A facilitative and enabling environment should be created in health facilities through ensuring availability of facemasks, providing training, removing job hindrances, assessing workloads, regular communication and promoting a safety culture (71). Health organisations and hospitals should ensure availability of facemasks and respirators for HCWs, particularly those

working in high risk wards and performing AGPs. Infection control training programs should be arranged for HCWs at induction and then on a yearly basis. Hospital administrators should ensure supportive monitoring and supervision in order to improve compliance with infection control practices and to promote a positive safety culture (71).

8.5 LACK OF STANDARDISED PRACTICES

Hospital and staff level studies confirmed that many standardised practices are lacking and components of respiratory protection programs, including certification, training, fit testing and medical evaluation of HCWs, are not implemented (5). Despite strong recommendations by the WHO and the CDC, there are no systems for regulation of respirators in the low resource countries and most hospitals do not use certified respirators (5, 6). Certification of respirators is necessary to ensure the quality of the product and the filtration efficacy of non-certified respirators is lower compared to certified respirators (5). A properly fitted respirator protects HCWs from airborne infections and respiratory aerosols generated during high risk procedures. A non-certified respirator may not perform better than a medical mask and may put HCWs at risk for infection.

Medical evaluation is a part of respiratory protection programs to ensure that employees are fit enough to use a respirator and that respirators are not harmful to the employees (72, 73). Medical evaluation is important for both employees and employer in terms of work output, occupational health and safety obligations and legal compensation issues. Training is an important component of respiratory protection programs and emphasises learning proper donning and doffing techniques to increase protection values of facemasks and respirators (69, 72). Proper doffing is important as wearers may not touch the outer surface of the respirator while doffing (68, 74). Fit testing is necessary to ensure the effectiveness of the respirator as a loosely fitted respirator will probably not perform any better than a medical mask (75). The risk of inhalation of infective particles is reduced if a respirator is properly fitted to the face. Fit checking is different from fit testing and required each time a respirator is donned (76). However, fit testing may not be available

in low resource countries and compliance with fit checking is low among HCWs even in high income countries (11, 77, 78).

Recommendation 6: Certification, training and fit testing should be implemented for respirator use

Comprehensive respiratory protection programs should be implemented for respirator use in health care settings. The certification process should be regulated by an authority in the country, such as NIOSH/OSHA in the US (72). Medical evaluation should be performed to ensure that HCWs are fit enough to use a respirator and may tolerate it without significant adverse events. During the medical evaluation process, individual (medical conditions) and work related factors (nature of work) should both be considered (73). All employees should be trained and fit tested at the time of new induction and then every year or more frequently if there is any change in the type of respirator being used or shape of face due to weight gain/loss (72). Both qualitative and qualitative fit tests should be performed to examine and estimate the leakage around the face/respirator seal (72, 79). HCWs should also perform fit check (user seal check) every time a respirator is donned. Both positive and negative pressure should be checked (76).

Recommendation 7: Respiratory protection programs need to be customised according to emergency situations such as outbreaks/pandemics

Although regulations, medical evaluation, training and fit testing improve the efficacy of respirators, they require additional time, expertise and resources (80). During emergency situations, such as outbreaks and pandemics, increased demand for training/fit testing may exceed the capacity of existing resources, particularly in low resource settings (8, 9, 68). Proper user seal check was performed in only 20% observations and respirators were properly donned in only 7% observations in California during the H1N1 influenza pandemic (68). HCWs faced problems with the fit testing as well (8, 9). Furthermore, a range of respirators of different sizes are required for fit testing, which could be a challenge during a pandemic. Respiratory protection programs need to be customised for

high demand situations and for low resource countries to ensure the proper use of respirators. Short training programs can be arranged for HCWs during emergency situations. Another option is to prepare online short videos and other easy accessible material to train large number of HCWs.

8.6 EXISTENCE OF NON-STANDARDISED PRACTICES:

The work presented in this thesis highlights that many non-standardised practices exist in low resource countries such as the use of cloth/paper masks and extended use/re-use of facemasks and respirators (6). Currently there is no evidence on the effectiveness of these practices (2) nor are they addressed in the policy documents (3). However, these practices are commonly reported during outbreaks and pandemics, when drugs and vaccines are not available and HCWs may be at the greatest risk (58-61).

Recommendation 8: Cloth masks should be used as a last option

Cloth masks may provide some protection against droplet infections (2), however they should be used as last option (1). We have shown that cloth masks may actually be detrimental and increase the risk of infection (81). Many health organisations (including the WHO, CDC, IOM and the US Association for Professionals in Infection Control and Epidemiology) also recommend cautious use of cloth masks during outbreaks/pandemics despite acknowledging a lack of efficacy data and the risk of infection to the wearer due to false sense of protection (13, 82, 83). If the use of cloth masks is deemed essential, HCWs should change them at least daily and should not use masks if they are wet or soiled. Cloth masks should be changed regularly and decontaminated using an approved method. If this is not possible, HCWs may wash their mask themselves with soap and water. However, hospitals should make it a priority to provide staff with disposable masks. Paper masks should not be used.

Recommendation 9: Re-use should be balanced against the risk of infection

Extended use of facemasks and respirators is generally not recommended, however it may be practiced in case of shortage of supplies and increased demand situations such as respiratory outbreaks in the hospital and pandemic influenza. In these situations, facemasks and respirators can be used for extended periods of time if they are not visibly soiled or damaged and recommended by the CDC (12). Extended use should be weighed against the risk of infection and self-contamination by touching a contaminated surface of the mask or respirator and subsequently touching the mucous membranes of the face or a hypothetical risk of re-aerosolisation of virus from a used product. In the case of extended use over multiple days, facemasks/respirators should be stored in a safe cabinet and should be used by the same wearer(12). Facemasks should not be stored in a pocket or hung around the neck and stored masks should not be visibly soiled or wet. Another option is to wear a medical mask over the respirator to extend the life of respirator, although adverse events may be increased (84).

8.7 NON-COMPLIANCE WITH RESPIRATORY PROTECTION

The study at staff level showed that compliance with the use of facemask is generally low and decreases over the time period studied (7). Continuous use of facemasks and respirators may cause psychological and physiological burdens on the wearer resulting in more adverse events (17, 85, 86). The occurrence of adverse events may result in to low compliance and should be studied further. Risk perception is another important determinant of adopting protective behaviour and a perception of increased risk is positively associated with compliance. Studies also show that compliance with the use of facemasks is associated with the nature of the disease, the infectiousness of patients and the performance of high risk procedures (11).

The PRECEDE model (Predisposing, Reinforcing and Enabling) framework has previously been tested to examine HCW use and compliance with universal precautions (71). The results showed that reinforcing factors; such as availability of PPE and fewer job

hindrances, and enabling factors such as: safety climate and regular feedback were significant predictors of compliance with PPE (71). In addition, the Health Belief Model (87) has also been applied to examine the compliance and use of facemasks during the SARS outbreak (88, 89). Among the components of the Health Belief Model, perceived susceptibility (vulnerability to acquiring SARS and close contact with a case), perceived benefits (that facemasks can prevent infection) and cues to action (someone asked them to use facemasks) were significant predictors of protective behaviour and use of facemasks (88).

Recommendation 10: New strategies should be developed to improve HCW compliance

New strategies should be developed to improve the compliance of HCWs with the use of various types of respiratory protection. Various health education approaches can be used to motivate HCWs (90). Given that organisational factors are key, it is essential that health care organisations work towards encouraging a safety climate (71). The management should have regular communication with HCWs, and regularly assess the workloads of HCWs and remove job related hindrances. Whether HCWs perceive susceptibility is also an important factor so hospitals should educate HCWs about the risks to their health. HCWs should also be educated on benefits of facemask use, as they have both positive ("90% effective") and negative ("I don't think it does anything") views about the efficacy of facemasks (11). Respirators are generally associated with more adverse events. In case of adverse effects with respirator use, alternative types may be used. Pre-existing medical conditions should be identified and medical evaluations should be performed before respirator use.

8.8 FUTURE RESEARCH NEEDS

As mentioned above, policies and practices differ due to a lack of high quality evidence around the efficacy, use and re-use of facemasks/respirators in health care settings. Most facemask research is carried out in high income countries; however some infections are more prevalent in low resource countries. It is therefore necessary to generate more

evidence around efficacy, use and re-use of various types of facemasks and in low resource health care settings.

Recommendation 11: Further research should be conducted to inform policy

Further research should be conducted to examine the efficacy of various types of facemasks and respirators to inform policy and guidelines. There are many limitations of facemask research and most studies are either observational or in-vivo. A control (no mask) arm cannot be included in clinical trials due to ethical reasons (92). Without a control arm, it is difficult to estimate the true efficacy of the intervention groups. In addition, the outcome may not be measured precisely in HCWs due to asymptomatic infections and household exposure to influenza and other infections (93, 94). Although most studies adjust for vaccination, hand washing and other confounders, presence of additional environmental (e.g. proper ventilation and high air exchange per hour) and administrative control measures (e.g. triage and disinfection of wards) at the hospitals may be difficult to control. Finally, facemask studies are expensive and a large number of participants are required to obtain sufficient power and clinically significant results. One option is to conduct a multi-year study to improve the power.

Cost-effectiveness studies are particularly important given the large price difference between N95 respirators and masks. In current cost-effective studies, the data used for the models are sparse, with assumptions about efficacy rather than RCT data and there is a need for better studies (95, 96). The cost of disposable and re-useable respirators should also be compared.

Recommendation 12: More research is needed to determine the suitability of non-standardised practices.

There is an urgent need for research to quantify the efficacy of cloth masks with large scale RCTs, and to study the various associated practices such as re-use and decontamination techniques globally. Currently, very little data are available around the efficacy and use of cloth masks in health care settings. Future research questions should

focus on clinical efficacy, filtration efficacy, length of use, methods of decontamination and fit testing.

Our data suggest that HCWs use facemasks and respirators for various lengths of time and that they may be used for extended periods of time (5, 6). There is no standard duration for the time period that facemasks and respirators can safely be used. It is therefore very difficult to set a cut off point for length of facemask use. Some studies show that adverse events increase with the use of facemasks for more than 8 hours (86). Other studies show that the compliance with facemasks reduces with an increase in wearing time and over the time period (17, 18). Further research should be conducted to determine the length of time that facemasks and respirators can be used.

Recommendation 13: Development of new respiratory protection devices to improve comfort and compliance

There is a need to develop new types of PPE, including facemasks/respirators. The recent Ebola outbreak has driven the development of new designs for facial protective devices and other PPE that can be used for long hours in hot and humid environments (97). According to the criteria laid down by the IOM, PPE should (a) “effectively reduce risk of disease or injury to HCWs”, (b) “minimise negative interactions with or effects on patients and their families and caregivers”, (c) “be acceptable and usable by HCWs in their daily tasks”, (d) “be practical regarding issues of cost, time and training” and (e) “be appropriate to the occupational risk being encountered” (50). New designs should focus on comfort so that facemasks/respirators may be used for long hours with fewer adverse events. Although respirators are available in various shapes (e.g. cup, flat fold and duck bill), medical and cloth masks are generally a flat fold shape. Other designs should be tested by improving the material of medical and cloth masks. Less focus has been placed on facial “fit” of medical and cloth masks and the substantial amount of air leaks around the face. The new designs need to account for these issues.

8.9 STRENGTHS AND LIMITATIONS OF THE RESEARCH

This thesis represents an important contribution to knowledge because it provides new data on the policies and practices around the use of facemasks and respirators in health care settings. Previous studies around the use of facemasks/respirators have mostly focused on high income countries, which have the resources available to develop and implement comprehensive infection control policies. I felt it was important to focus on low and middle resource settings, which have varied factors impacting their ability to use respiratory protection. To date, there have been very few studies that have comprehensively examined the policies and practices in place regarding the use and re-use of facemasks and respirators in low resource countries. This thesis particularly focused on the use of cloth masks, which although widely used by hospital staff in low/middle income countries, have never been studied.

There are limitations of this work that need to be noted. I reviewed the publically available policies and guidelines in 2013 and therefore some updated guidelines may not be included. However, I have been regularly searching the updated recommendations from publicly available sources. Due to resource constraints, we only included three Asian countries in the health department and hospital surveys. There may be different policies and practices in other low resource countries in Africa and South America. Limitations of cross sectional surveys such as recall and information biases should also be considered when interpreting the results. Actual practices of HCWs could also not be verified by participant observations or other methods due to resource and time constrains. Finally, many HCWs work in the community setting, including those working in homes and other health organisations, which were not included in this study. Policies and practices applicable to HCWs working in non-clinical areas (e.g. administrative areas and offices) and outside the hospital (e.g. nursing homes and ambulances) should also be explored (8).

8.10 CONCLUSION

This research provides new data around the factors impacting the use of facemasks and respirators in resource poor settings. Facemask policies in low/middle income countries vary and are not translated into clinical practice. In addition, existing practices are influenced by the availability of facemasks and respirators, policies at the organizational level (5, 6) and preferences, perceptions and compliance at the individual level (6). Understanding these factors will assist with the development of strategies to improve staff compliance with respiratory protection. A comprehensive and uniform policy should be developed regarding the use and re-use of facemasks and respirators in health care settings and hospitals should comply with these policies. More clinical trials need to be conducted to explore the efficacy of various types of facemasks and respirators, particularly trials that examine the efficacy of cloth masks and powered air purifying respirators. Currently, there are many non-standardised practices being implemented in practice, which are putting HCWs at risk and require further research.

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Appendix 1:

Publications arising from this thesis

(Papers are not annexed due to copy right)

1. **Chughtai AA**, Seale H, MacIntyre CR. Availability, consistency and evidence-base of policies and guidelines on the use of mask and respirator to protect hospital health care workers: a global analysis. BMC research notes. 2013;6:216.

2. **Chughtai AA**, MacIntyre CR, Zheng Y, Wang Q, Toor ZI, Dung TC, et al. Examining the policies and guidelines around the use of masks and respirators by healthcare workers in China, Pakistan and Vietnam. Journal of Infection Prevention. 2014:1-7. DOI:1757177414560251.

3. **Chughtai AA**, Seale H, Chi Dung T, Maher L, Nga PT, MacIntyre CR. Current practices and barriers to the use of facemasks and respirators among hospital-based health care workers in Vietnam. American journal of infection control. 2015;43(1):72-7.

4. **Chughtai AA**, Seale H, MacIntyre CR. Use of cloth masks in the practice of infection control–evidence and policy gaps. International Journal of Infection Control. 2013;9(3):1-12.

5. **Chughtai AA,** MacIntyre CR, Ashraf MO, Zheng Y, Yang P, Wang Q, , Dung TC, Hien NT, Seale H. Practices around the use of facemasks and respirators amongst hospital healthcare workers (HCWs) in three diverse populations. 2015. American journal of infection control (In press).

Appendix 2:

Publications associated with this thesis

(Papers are not annexed due to copy right)

1. MacIntyre CR, Seale H, Dung TC, Hien NT, Nga PT, **Chughtai AA**, Rahman B, Dwyer DE, Wang Q. A randomised clinical trial of medical masks and cloth masks in healthcare workers.2015. BMJ Open. 2015. 5: e006577.

2. MacIntyre CR, **Chughtai AA**. Face masks for the prevention of infection in healthcare and community settings. 2015. BMJ 350:h694

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the use of masks and respirators in the hospital setting. Journal of Infection Control 2014;1(i):1-8.

7. Bui C, Bethmont A, **Chughtai AA**, Gardner L, Sarkar S, Hassan S, et al. A Systematic Review of the Comparative Epidemiology of Avian and Human Influenza A H5N1 and H7N9 - Lessons and Unanswered Questions. Transboundary and emerging diseases. 2015:1-19. doi:10.1111/tbed.12327