**Supplementary Appendices**

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APPENDIX A: supplementary figures

Figure S1. Risk of bias in RCTs



The risk of bias within and across the RCTs included in this review was assessed using the Cochrane Collaboration’s Risk of Bias tool.(1)

(A) RCTs received a high (red), low (green) or uncertain (yellow) risk of bias score for each of the following domains:

I) Random sequence generation;

II) Allocation concealment;

III) Blinding of participants, personnel and outcome assessors (clinical outcomes);

IV) Blinding of participants, personnel and outcome assessors (laboratory-confirmed outcomes);

VI) Incomplete outcome data;

VII) Selective outcome reporting;

VIII) Other potential threats to validity;

(B) Percentage of RCTs with high, low or uncertain risk of bias in each domain.

Figure S2. Publication bias

Potential publication bias was assessed separately in RCTs and observational studies using funnel plots. Unadjusted effect estimates from individual studies were plotted against their standard error. Solid and dashed lines represent the summary effect estimate and its 95% confidence intervals for different values of the standard error, respectively. To identify potential publication bias, the Harbord test of small-study effects was used to assess funnel plot asymmetry.

(A) Funnel plot assessing publication bias in RCTs investigating the effectiveness of different types of respiratory PPE against clinical (influenza-like illness and clinical respiratory illness) or laboratory-confirmed outcomes (influenza or other viral or bacterial respiratory infections); Harbord’s estimated bias coefficient: -0.59; p=0.592.

(B) Funnel plot assessing publication bias in RCTs comparing the effectiveness of N95 respirators and medical masks against clinical (influenza-like illness and clinical respiratory illness) or laboratory-confirmed outcomes (influenza or other viral or bacterial respiratory infections); Harbord’s estimated bias coefficient: 0.42; p=0.633.

(C) Funnel plot assessing publication bias in observational studies investigating the effectiveness of different types of respiratory PPE against SARS infection; Harbord’s estimated bias coefficient: -0.45; p=0.481.

APPENDIX B: Tables and supplementary information

Tables

Table 1. Overview of the meta-analyses performed by type of respiratory PPE (rPPE) and respiratory outcomes assessed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study design** | **Principal summary measure** | **rPPE assessed in meta-analysis** | **Control** | **Outcomes** | **Figure** |
| **RCTs** | Risk ratio | N95 respirator or medical mask | No rPPE | Clinical | Clinical respiratory infection (CRI) | 2A |
| Influenza-like illness (ILI) | 2B |
| Laboratory-confirmed | Viral respiratory illness (VRI) | 2C |
| N95 respirator | Medical mask | Clinical | Clinical respiratory infection (CRI) | 3A |
| Influenza-like illness (ILI) | 3B |
| Laboratory-confirmed | Bacterial colonization (BRI) | 4A |
| Influenza | 4B |
| Viral respiratory illness (VRI) | 4C |
| **Observational** (2003 SARS pandemic) | Odds ratio (and range of corresponding risk ratios) | Any type of rPPE | No rPPE | Laboratory-confirmed | SARS infection | 5A |
| Medical mask  | No rPPE | 5B |
| N95 respirator | No rPPE | 5C |
| N95 respirator | Medical mask  | 5D |

Table 2. Case-control studies assessing the association of SARS infection and mask use (n=8)

Odds Ratios (ORs) for wearing masks among cases or controls using “wearing no mask” as reference category, unless otherwise stated.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Cases** | **Controls** | **Mask** | **% among** | **Unadjusted** | **Adjusted** |
| **Cases** | **Controls** | **OR** | **95% CI** | **p-valuea** | **OR** | **95% CI** | **p-value** |
| Chen 200952 | Sero-positive HCWs who tended to SARS patients (n=91) | Sero-negative HCWs who tended to SARS patients (n=657) | **Cotton** double-layeredref: single-layered | 64.8%(59/91) | 82.3%(541/657) | 0.40 | 0.24–0.66 | <0.001 |  |  |  |
| Lau 200453 | HCWs who worked in SARS wards and were hospitalized with laboratory-confirmed SARS; 48 medical and nursing staff and 24 assistants).(n=72) | HCWs working in the same ward, in the same job position and in proximity of the case-patient before he became ill. No ILI or SARS symptoms  (n=143) | **N95** or **surgical**(contact with SARS patients)ref: inconsistent use | 98.6%(71/72) | 100.0%(143/143) | n.a. | n.a. | 0.335 | 0.50 | 0.0–20.0 | 0.667 |
| **N95** or **surgical**(contact with general patients)ref: inconsistent use | 97.2%(70/72) | 99.3%(142/143) | 0.25 | 0.00–4.84 | 0.260 | 0.25 | 0.00–4.76 | 0.519 |
| **N95** or **surgical**(no contact to patients)ref: inconsistent use | 94.4%(68/72) | 97.9%(140/143) | 0.36 | 0.05–2.23 | 0.227 | 0.41 | 0.06–2.43 | 0.420 |
| **N95** (contact with SARS patients)ref: surgical or inconsistent N95  | 90.3%(65/72) | 95.8%(137/143) | 0.41 | 0.11–1.48 | 0.109 | 0.35 | 0.07–1.43 | 0.168 |
| **N95** (contact with general patients)ref: surgical or inconsistent N95 | 95.8%(69/72) | 96.5%(138/143) | 0.83 | 0.16–5.53 | 1.000 | 0.78 | 0.10–6.25 | 1.000 |
| **N95** (no contact to patients)ref: surgical or inconsistent N95 | 83.3%(60/72) | 90.2%(129/143) | 0.54 | 0.22–1.37 | 0.144 | 0.55 | 0.21–1.39 | 0.232 |
| Liu 200946 | HCWs diagnosed as probable SARS cases between 5 March and 17 May, 2003; all cases and controls confirmed by anti-SARS IgG-ELISA (n=51) | HCWs working in the same hospital who had self-reported close exposure (WHO) in the same period but were not diagnosed with SARS(n=426) | **Surgical** 12-layerref: different or no mask | 15.7%(8/51) | 27.0%(115/426) | 0.50 | 0.20–1.13 | 0.081 | 0.22 | 0.08–0.62 | 0.004 |
| **Surgical** 16-layerref: different or no mask | 29.4%(15/51) | 60.8%(259/426) | 0.27 | 0.13–0.52 | < 0.001 | 0.17 | 0.07–0.41 | <0.001 |
| **N95**ref: different or no mask | 3.9%(2/51) | 7.3%(31/426) | 0.52 | 0.06–2.16 | 0.560 |  |  |  |
| **Disposable**ref: different or no mask | 21.6%(11/51) | 19.7%(84/426) | 1.11 | 0.50–2.34 | 0.755 |  |  |  |
| **Multiple layers** of any maskref: 1 layer | 76.9%(20/26) | 94.3%(266/282) | 0.20 | 0.07–0.70 | 0.001 | 0.41 | 0.17–0.97 | 0.026 |
| Ma 200447 | HCWs from 5 hospitals diagnosed with SARS (Chinese MoH definition) (n=47) | HCWs working in the same departments in the same period not diagnosed with SARS (n=426) | **Any mask** |  |  | 0.24 | 0.09–0.64 | 0.004 |  |  |  |
| **Surgical** ≤12 layers |  |  |  |  |  | 76.7 | 16.7–351.3 | <0.001 |
| **Surgical** ≤16 layersref: surgical ≤12 layers |  |  | 0.06 | 0.03–0.15 | <0.001 |  |  |  |
| **Disposable** ≤16 layersref: surgical ≤12 layers |  |  | 0.13 | 0.05–0.34 | <0.001 |  |  |  |
| **N95/ pig-mouth mask** ≤16 layersref: surgical ≤12 layers |  |  | <0.001b | 0.00–0.33 | 0.001 |  |  |  |
| Nishiura 200548  | HCWs with laboratory-confirmed SARS by ELISA; 28 hospital HCWs and 1 patient relative(n=29) | HCWs >20 years who were exposed to confirmed cases or patients’ relatives; 57 hospital HCWs and 41 patient relatives(n= 98) | **Surgical**(stage I)d | 32.0(8/25) | 38.9(35/90) | 0.74 | 0.25–2.05 | 0.529 | 0.29 | 0.11–0.73 | 0.009 |
| **Surgical**(stages II and III) d | 25.0(1/4) | 96.2(25/26) | 0.01 | 0.00–0.44 | 0.004 | 0.01 | 0.00–0.30 | 0.001 |
| Seto 200349 | HCWs exposed to 11 symptomatic index patients (patient care ≤0.91m), who were diagnosed with SARS 2–7 days after exposure and had no exposure outside the hospital (n=13) | HCWs with the same exposure characteristics who did not develop SARS (n=241)  | **Any mask** | 15.4(2/13) | 70.1(169/241) | 0.08 | 0.01–0.37 | <0.001 | 0.08 | 0.02–0.33 | 0.011 |
| **Paper** | 15.4(2/13) | 26.5(26/98) | 0.50 | 0.05–2.56 | 0.511 |  |  |  |
| **Surgical** | 0(0/11) | 41.5(51/123) | 0.0 | 0.00–0.50 | 0.007 |  |  |  |
| **N95** | 0(0/11) | 56.1(92/164) | 0.0 | 0.00–0.28 | <0.001 |  |  |  |
| Teleman 200450 | HCWs with laboratory-confirmed SARS by serology admitted between 1 and 31 March, 2003(n=36) | Healthy HCWs from SARS-affected wards reporting exposure (<1 m) from a confirmed patient (n=50) | **N95** | 8.3(3/36) | 46.0(23/50) | 0.11 | 0.02–0.42 | <0.001 | 0.1 | 0.02–0.86 | 0.04 |
| Yin 200451 | HCWs from 10 hospitals who accessed isolation units and/or attended SARS patients and were diagnosed with SARS (Chinese MoH definition)(n=77)  | HCWs with the same exposure characteristics but not diagnosed with SARS(n=180) | **Any mask** | 88.3(68/77) | 98.9(178/180) | 0.08 | 0.01–0.43 | <0.001 | 0.78**c** | 0.60–0.99 | <0.05 |
| **Surgical** ≤12 layers | 83.6(46/55) | 98.7(156/158) | 0.07 | 0.01–0.34 | <0.001 |  |  |  |
| **Disposable** | 71.0(22/31) | 91.7(22/24) | 0.22 | 0.02–1.28 | 0.089 |  |  |  |
| **Frequency of mask use** |  |  |
| **Frequent** (any mask)ref: never worn |  |  | 0.13 |  |  |  |  |  |
| **Always** (any mask)ref: never worn |  |  | 0.07 |  |  |  |  |  |

a for χ2-test or Fisher’s exact test (for values <5)

HCWs= healthcare workers

SARS= Severe acute respiratory syndrome

ILI= influenza-like illness

IgG ELISA= Immunoglobulin G enzyme-linked immunosorbent assay

WHO= World Health Organization

Ref= reference category for OR

b study reported “OR=0.0”

**c** unclear whether adjusted OR was reported for “any mask” or surgical ≤12 layer mask

d Stage I: from admission of the index case to onset of secondary cases; stages II and III: from suspicion of nosocomial spread to local eradication

MoH= ministry of health

Table 3. Retrospective cohort studies assessing the risk of SARS infection among HCWs according to mask wearing habits (n=4)

Risk Ratios (RRs) for SARS infection among HCWs wearing or not wearing a mask using “SARS negative” as reference category, unless otherwise stated.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Cohort** | **Outcome** | **Mask** | **% SARS-positives****among HCWs wearing** | **RR** | **95% CI** | **p-valueb** |
| **Mask** | **No maska** |
| Loeb 200437 | Nurses who worked at least one shift while SARS-patients were present and entered patient’s room(n=32)  | Risk of laboratory-confirmed SARS infection among HCWs consistently or inconsistently wearing a mask  | **Surgical** or **N95** | 13.0(3/23) | 55.6(5/9) | 0.23 | 0.07–0.78 | 0.023 |
| **N95** | 12.5(2/16) | 55.6(5/9) | 0.23 | 0.05–0.93 | 0.058 |
| **Surgical**  | 25.0(1/4) | 55.6(5/9) | 0.45 | 0.07–2.71 | 0.5594 |
| Risk of laboratory-confirmed SARS infection among HCWs wearing a N95 or a surgical mask | **N95** control: surgical | 12.5(2/16) | 25.0(1/4) | 0.50 | 0.06–4.23 | 0.509 |
| Nishiyama 200854 | Staff who had contact with SARS patients and did or did not subsequently develop SARS.(n=85) | Risk of laboratory-confirmed SARS infection among HCWs always wearing a mask | **Mask** ref: sometimes |  |  | 0.34‡ | 0.09–1.37‡ | 0.13c |
| **Mask** ref: never |  |  | 0.08‡ | 0.01–0.50‡ | <0.01c |
| Scales 200338 | Quarantined ICU staff who entered an undiagnosed SARS index patient’s room (n=31) | Risk of SARS infection (WHO definition) among HCWs wearing or not wearing a mask  | **Surgical** or **N95** | 23.1(3/13) | 16.7(3/18) | 1.38 | 0.33–5.80 | 0.676 |
| HCWs present during NPPV on a SARS patient(n=22) | **N95** | 20.0(1/5) | 17.6(3/17) | 1.13 | 0.15–8.64 | 1.000 |
| Wilder-Smith 200539 | HCWs who had contact with any of 3 SARS-patients before infection control measures became mandatory(n=98) | Risk of penumonic SARSd among HCWs wearing or not wearing a mask  | **N95** | 12.5(3/24) | 52.3(34/65) | 0.24 | 0.08–0.71 | <0.001 |
| Risk of asymptomatic SARSd among HCWs wearing or not wearing a mask  | 12.5(3/24) | 8.8(3/34) | 1.42 | 0.31–6.43 | 0.684 |
| Risk of pneumonic SARSd among HCWs wearing or not wearing a maskref: asymptomatic SARS | 50.0(3/6) | 91.9(34/37) | 0.54 | 0.24–1.22 | 0.027 |

**a** except for (Loeb 2004) rows 1-3, where control = wearing mask inconsistently

b for χ2-test or Fisher’s exact test (for values <5)

c Adjusted for occupation, type of patient contact, severity of patient symptoms, hand washing, attendance of infection control lecture

d laboratory-confirmed by serology

ICU= intensive care unit

SARS= Severe acute respiratory syndrome

HCWs= healthcare workers

NPPV= noninvasive positive-pressure ventilation

WHO= World Health Organization

Ref= reference category for RR

Supplementary information: search strategy

Table S1. Search terms used for literature search

|  |  |  |
| --- | --- | --- |
| **Intervention** | **Outcome** | **Population** |
| mask\*, facemask\*, face mask, face masks, medical mask, medical masks, medical facemask, medical facemasks, medical face mask, medical face masks, surgical mask, surgical masks, surgical facemask, surgical facemasks, surgical face mask, surgical face masks, N95, N97, N99, FFP, FFP1, FFP2, FFP3, respirator, respirators, respiratory protection, respiratory protective device, respiratory protective devices, personal protective equipment, PPE, face protection, airborne precaution, airborne precautions, droplet precaution, droplet precautions, non-pharmaceutical intervention, non-pharmaceutical interventions | infection\*, emerging infection, emerging infections, respiratory infection, respiratory infections, respiratory tract infection, respiratory tract infections, acute respiratory infection, acute respiratory infections, ARI, acute respiratory tract infection, acute respiratory tract infections, upper respiratory tract infection, upper respiratory tract infections, URTI, common cold, influenza, parainfluenza, flu, pandemic influenza, SARS, influenza-like illness, ILI, rhinovir\*, adenovir\*, coronavir\*, RSV, respiratory syncytial virus, respiratory syncytial viruses, infection control, communicable disease control, infectious disease transmission, communicable disease transmission, cross infection, cross infections, cross-infection, cross-infections, HCAI, healthcare-associated infection, healthcare-associated infections, health care-associated infection, health care-associated infections, health-care-associated infection, health-care-associated infections | HCW\*, healthcare worker, healthcare workers, health care worker, health care workers, health-care worker, health-care workers, healthcare professional, healthcare professionals, health care professional, health care professionals, health-care professional, health-care professionals, nurse\*, doctor\*, practicioner\*, practitioner\*, staff, healthcare personnel, health care personnel, health-care personnel |

Table S2. Search strings for the three databases

|  |  |
| --- | --- |
| **Database** | **Search string** |
| PubMed | (mask\*[MeSH Terms] OR mask\*[Title/Abstract] OR facemask\*[Title/Abstract] OR “face mask”[Title/Abstract] OR “face masks”[Title/Abstract] OR “medical mask”[Title/Abstract] OR “medical masks”[Title/Abstract] OR “surgical mask”[Title/Abstract] OR “surgical masks”[Title/Abstract] OR “surgical facemask”[Title/Abstract] OR “surgical facemasks”[Title/Abstract] OR “surgical face mask”[Title/Abstract] OR “surgical face masks”[Title/Abstract] OR N95[Title/Abstract] OR N97[Title/Abstract] OR N99[Title/Abstract] OR FFP[Title/Abstract] OR FFP1[Title/Abstract] OR FFP2[Title/Abstract] OR FFP3[Title/Abstract] OR respirator[Title/Abstract] OR respirators[MeSH Terms] OR respirators[Title/Abstract] OR “respiratory protection”[Title/Abstract] OR “respiratory protective device”[Title/Abstract] OR “respiratory protective devices”[MeSH] OR “respiratory protective devices”[Title/Abstract] OR “personal protective equipment”[Title/Abstract] OR PPE[Title/Abstract] OR “face protection”[Title/Abstract] OR “airborne precautions”[Title/Abstract] OR “droplet precautions”[Title/Abstract] OR “non-pharmaceutical intervention”[Title/Abstract] OR “non-pharmaceutical interventions”[Title/Abstract]) AND (infection\*[MeSH Terms] OR infection\*[Title/Abstract] OR “emerging infection”[Title/Abstract] OR “emerging infections” [Title/Abstract] OR “respiratory infection”[Title/Abstract] OR “respiratory infections” [Title/Abstract] OR “respiratory tract infection”[Title/Abstract] OR “respiratory tract infections”[MeSH Terms] OR “respiratory tract infections” [Title/Abstract] OR “acute respiratory infection”[Title/Abstract] OR “acute respiratory infections” [Title/Abstract] OR ARI[Title/Abstract] OR “acute respiratory tract infection”[Title/Abstract] OR “acute respiratory tract infections” [Title/Abstract] OR “upper respiratory tract infection”[Title/Abstract] OR “upper respiratory tract infections” [Title/Abstract] OR URTI[Title/Abstract] OR “common cold”[MeSH Terms] OR “common cold”[Title/Abstract] OR influenza[MeSH Terms] OR influenza[Title/Abstract] OR parainfluenza[MeSH Terms] OR parainfluenza[Title/Abstract] OR flu[MeSH Terms] OR flu[Title/Abstract] OR “pandemic influenza”[Title/Abstract] OR SARS[Title/Abstract] OR “influenza-like illness”[Title/Abstract] OR ILI[Title/Abstract] OR rhinovir\*[MeSH Terms] OR rhinovir\*[Title/Abstract] OR adenovir\*[MeSH Terms] OR adenovir\*[Title/Abstract] OR coronavir\*[MeSH Terms] OR coronavir\*[Title/Abstract] OR RSV[Title/Abstract] OR “respiratory syncytial virus”[Title/Abstract] OR “respiratory syncytial viruses”[MeSH Terms] OR “respiratory syncytial viruses”[Title/Abstract] OR “infection control”[MeSH Terms] OR “infection control”[Title/Abstract] OR “communicable disease control”[MeSH Terms] OR “communicable disease control”[Title/Abstract] OR “infectious disease transmission”[Title/Abstract] OR “communicable disease transmission”[Title/Abstract] OR “cross infection”[MeSH Terms] OR “cross infection”[Title/Abstract] OR “cross infections”[Title/Abstract] OR “cross-infection”[MeSH Terms] OR “cross-infection”[Title/Abstract] OR “cross-infections”[Title/Abstract] OR HCAI[Title/Abstract] OR “healthcare-associated infection”[Title/Abstract] OR “healthcare-associated infections”[Title/Abstract] OR “health care-associated infection”[Title/Abstract] OR “health care-associated infections”[Title/Abstract]) OR “health-care-associated infection”[Title/Abstract] OR “health-care-associated infections”[Title/Abstract] AND (HCW\*[Title/Abstract] OR “healthcare worker”[Title/Abstract] OR “healthcare workers”[Title/Abstract] OR “health care worker”[Title/Abstract] OR “health care workers”[Title/Abstract] OR “health-care worker”[Title/Abstract] OR “health-care workers”[Title/Abstract] OR “healthcare professional”[Title/Abstract] OR “healthcare professionals”[Title/Abstract] OR “health care professional”[Title/Abstract] OR “health care professionals”[Title/Abstract] OR “health-care professional”[Title/Abstract] OR “health-care professionals”[Title/Abstract] OR nurse\*[MeSH Terms] OR nurse\*[Title/Abstract] OR doctor\*[Title/Abstract] OR practicioner\*[Title/Abstract] OR practitioner\*[Title/Abstract] OR staff[Title/Abstract] OR “healthcare personnel”[Title/Abstract] OR “health care personnel”[Title/Abstract] OR “health-care personnel”[Title/Abstract]) |
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| Web of Science | **TS=**(mask\* OR facemask\* OR “face mask“ OR “face masks“ OR “medical mask“ OR “medical masks“ OR “medical facemask“ OR “medical facemasks“ OR “medical face mask“ OR “medical face masks“ OR “surgical mask“ OR “surgical masks“ OR “surgical facemask“ OR “surgical facemasks“ OR “surgical face mask“ OR “surgical face masks“ OR N95 OR N97 OR N99 OR FFP OR FFP1 OR FFP2 OR FFP3 OR respirator OR respirators OR “respiratory protection“ OR “respiratory protective device“ OR “respiratory protective devices“ OR “personal protective equipment“ OR PPE OR “face protection“ OR “airborne precaution“ OR “airborne precautions“ OR “droplet precaution“ OR “droplet precautions“ OR “non-pharmaceutical intervention“ OR “non-pharmaceutical interventions“) AND TS=(infection\* OR “emerging infection“ OR “emerging infections“ OR “respiratory infection“ OR “respiratory infections“ OR “respiratory tract infection“ OR “respiratory tract infections“ OR “acute respiratory infection“ OR “acute respiratory infections“ OR ARI OR “acute respiratory tract infection“ OR “acute respiratory tract infections“ OR “upper respiratory tract infection“ OR “upper respiratory tract infections“ OR URTI OR “common cold“ OR influenza OR parainfluenza OR flu OR “pandemic influenza “OR SARS OR “influenza-like illness“ OR ILI OR rhinovir\* OR adenovir\* OR coronavir\* OR RSV OR “respiratory syncytial virus“ OR “respiratory syncytial viruses“ OR “infection control“ OR “communicable disease control“ OR “infectious disease transmission“ OR “communicable disease transmission“ OR “cross infection“ OR “cross infections“ OR “cross-infection“ OR “cross-infections“ OR HCAI OR “healthcare-associated infection“ OR “healthcare-associated infections“ OR “health care-associated infection“ OR “health care-associated infections“OR “health-care-associated infection“ OR “health-care-associated infections“) **AND TS**=(HCW\* OR “healthcare worker” OR “healthcare workers” OR “health care worker” OR “health care workers” OR “health-care worker” OR “health-care workers” OR “healthcare professional” OR “healthcare professionals” OR “health care professional” OR “health care professionals” OR “health-care professional” OR “health-care professionals” OR nurse\* OR doctor\* OR practicioner\* OR practitioner\* OR staff OR “healthcare personnel” OR “health care personnel” OR “health-care personnel”)  |

 Supplementary information: data extracted from included studies

### Randomized controlled trials (RCTs)

Table S3. Summary of RCTs assessing the effectiveness of masks and respirators against respiratory infection (n=6)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Population** | **Study design** | **Intervention(s)** | **Comparison group(s)** | **Primary outcomes** | **Additional outcomes** | **Follow-up** | **Analysis** | **Results** | **Comments** |
| **MacIntyre 2011(2)****Journal**: Influenza Other Resp Diseases**Country:** China**Study period**: December 2008 to January 2009 | Nurses or doctors who worked full-time in EDs or respiratory wards in 15 Beijing hospitals. | 3-arm cluster randomization at hospital level, 4-week follow-up plus 1 week without masks for symptom development.Convenience sample of HCWs who did not routinely wear masks used as control. | Fit-tested (n=461) or non-fit-tested (n=488) N95 respirator, worn at every shift. | Medical masks (3M) (n=492); convenience sample (n=481). | CRI; ILI; laboratory-confirmed viral respiratory infection; laboratory-confirmed influenza A or B. | Observed compliance with mask use (80% or more of work shift hours). | Participants contacted daily by phone or face-to-face by head nurse to actively identify incident cases of respiratory infection, plus daily site monitoring through District CDC. Swabs of bothtonsils and the posterior pharyngeal wall collected from symptomatic individuals. | ITT analysis. N95 groups combined and compared with medical mask group. Differences in proportions using χ2-test. Random effects logistic regression to adjust for clustering. | CRI: OR=0.62 (0.28-1.35); ILI: 0.52 (0.10-2.57); Lab-confirmed virus: OR=0.54 (0.21-2.36); Influenza: OR=0.31 (0.07-1.32). |  |
| **MacIntyre 2013(3)****Journal**: Am J Respir Crit Care Med**Country:** China**Study period**: December 2009 to February 2010 | HCWs in 68 EDs and respiratory wards of 19 tertiary hospitals in Beijing. | 3-arm cluster randomization at ward level, 4-week follow-up plus 1 week without masks for symptom development. | Continuous (n=581) or targeted (n=516) use of N95 respirators. | Medical masks (3M) (n=572). | CRI; ILI; laboratory-confirmed viral respiratory infection; laboratory-confirmed influenza A/B in symptomatic participants; laboratory-confirmed bacterial colonization in symptomatic participants.  | Self-reported adherence to mask or N95 use. | Participants contacted daily for symptoms, swabs of tonsils and posterior pharyngeal wall collected on same day.Adherence to mask use assessed through validated diary card collected at the end of each day. | ITT analysis. χ2-tests and ICCs for event rates across groups. Kaplan-Meier survival curves and HRs from multivariable Cox regression with robust standard errors. Sensitivity analysis using per-protocol analysis. | CRI: N95 vs medical masks: HR=0.39 (0.21-0.71); targeted N95 vs medical masks: HR=0.70 (0.39-1.24); Bacterial: N95 vs medical masks: HR=0.40 (0.21-0.73); targeted N95 vs medical masks:HR=0.70 (0.4-1.24) | Targeted N95 arm had highest compliance (82%); Medical masks (66%); N95 (57%). |
| **MacIntyre 2014(4)****Journal**: Prev Med**Country:** China**Study period**: December 2008 to January 2009 | Nurses or doctors who worked full-time in EDs or respiratory wards in 15 Beijing hospitals. | 3-arm cluster randomization at hospital level, 4-week follow-up plus 1 week without masks for symptom development. Convenience sample of HCWs who did not routinely wear masks used as control. | Fit-tested or non fit-tested N95 respirator, worn at every shift (n=949). | Medical masks (3M) (n=492); Convenience controls (n=481). | Laboratory-confirmed bacterial colonization in symptomatic patients.  | Co-colonization with >1 bacteria; bacterial-viral co-infection. | Participants contacted daily to identify incident cases of CRI. Nose and throat swab collected from symptomatic patients. | ITT analysis. N95 groups combined. RR for N95 vs medical mask. Efficacy of N95 and medical masks against control. Multivariable log binomial model accounting for hospital-level clustering, adjusting for potential confounders. | Bacterial detection: N95=2.8%; medical mask=5.3%; control=7.5%. Efficacy of N95: 46% against medical mask, 62% against control. Medical mask not significantly different from control. Multivariable cluster adjusted results: N95 vs control=66% for bacterial infection. | Same study as (2), conducted in a different influenza season? Control group selected from different hospitals where mask use was not routine. |
| **MacIntyre 2015(5)****Journal**: BMJ Open**Country:** Vietnam**Study period**: March 2011 for 4 weeks | HCWs in 14 hospitals in Hanoi. | 3-arm RCT with cluster-randomization at ward level, 4-week follow-up plus 1 week without masks for symptom development. | Medical masks (n=580); cloth masks (n=569). | Routine practice (n=458). | CRI; ILI; laboratory-confirmed viral respiratory infection. | Self-reported compliance with mask use (70% or more of work shift hours). | Participants contacted daily for symptoms, swabs of tonsils and posterior pharyngeal wall collected on same day.Adherence to mask use assessed through validated diary card collected at the end of each day. | ITT analysis. RR estimated using log-binomial GEE model adjusting for clustering (ref=medical mask). Post-hoc analysis combining intervention arms with medical and cloth mask users from control group, with no adjustment for clustering. | Cloth masks: CRI: RR=1.57 (0.99-2.48); ILI: RR=13.25 (1.74-100.97); viral infection: RR=1.66 (0.95-2.91); Control: CRI: RR=1.45 (0.88-2.37); ILI: RR=2.80 (0.40-36.40); viral infections: RR=1.20 (0.64-2.26);compliance was 56% in intervention groups and 23% in control group. | Unclear eligibility criteria for hospitals/wards. No description of 14% non-participants or reasons for non-participation. Filtration study showed very poor performance of both cloth (97% penetration) and medical (44% penetration) masks relative to N95 (0.01%). |
| **Loeb 2009(6)****Journal**: JAMA**Country:** Canada**Study period**: September 2008 to April 2009 | Nurses in 8 Ontario tertiary care hospitals | 2-arm non-inferiority RCT with blinded allocation and lab testing. Randomization was stratified by hospital and done in blocks of 4 participants. | Surgical mask (n=225) when caring for patients with febrile respiratory illness (13 withdrew prior to follow-up). | N95 respirators (n=221) when caring for patients with febrile respiratory illness (11 withdrew prior to follow-up). | ILI; laboratory-confirmed influenza infection; non-influenza viral infections as detected by PCR. | Serological infection defined as 4-fold increase in influenza-specific HA assay titre between baseline and end of study samples; work-related absenteeism and physician visits for respiratory infection. Observed compliance. | Participants assessed for signs and symptoms of influenza twice weekly using web questionnaire, and nasal swab obtained from symptomatic participants. | ITT analysis. Difference in incidence of lab-confirmed influenza between arms using Fisher's exact test. Surgical masks considered non-inferior if lower limit of 95% CI for risk difference was greater than -9%. | 23.6% influenza in surgical mask group vs 22.9% in N95 group (RD=-0.73%).  | Trial stopped early because of start of pH1N1 epidemic. |
| **Jacobs 2009(7)****Journal**: Am J Infect Control**Country:** Japan**Study period**: January 2008 for 77 days | HCWs at 520-bed tertiary care hospital in Tokyo. | 2-arm RCT with block randomization stratified by job category (nurses, doctors, other). | Surgical masks (MA-3) while on hospital property (n=17). | Refrained from wearing mask while on hospital property unless required to do so as part of job duties (n=15). | URI based on daily self-reporting of 8 symptoms.  |  | Daily health diary of participants recording any of 8 symptoms of URI on a 4-point scale (0, none; 1, mild; 2, moderate; 3, severe; for fever: 0, absent; 1, present). URI defined as a 2-day total symptom score >14. | ITT analysis. Fisher's exact test for differences in URI between arms. | 1/17 in mask and 1/15 in non-mask group had URI. | Very small study (sample size large enough to detect absolute reduction in URI of 60% in mask group), no details of how block randomization was done, no statistical testing of primary outcome, and other analyses presented appear to be post-hoc. |

ED= emergency department

CRI= clinical respiratory illness

ILI= influenza-like illness

CDC= Centers for Disease Control and Prevention

ITT= intention to treat

OR= odds ratio

HR= hazard ratio

RR= risk ratio

GEE= generalised estimating equation

PCR= polymerase chain reaction

HA= haemagglutination assay

RD= risk difference

pH1N1= pandemic H1N1 influenza

URI= upper respiratory tract infection

### Observational studies

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#### Severe Acute Respiratory Syndrome (SARS)

Table S4. Summary of case-control studies assessing the effectiveness of masks and respirators against SARS infection (n=8)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Mask** | **Cases** | **Controls** | **Ascertainment of exposure** | **Assessment of outcome** | **Analysis Methods** | **Response rates** | **Main conclusions** | **Limitations** |
| **Chen 2009(8)****Journal:** BMC Public Health **Location:** Two University hospitals in Guangzhou, China**SARS outbreak:** early 2003 | Multi-layered cotton mask. | HCWs who tended to SARS patients and were sero-positive against SARS.(n=91) | HCWs who tended to SARS patients but were not sero-positive against SARS.(n=657) | Standardized interview with structured questionnaire conducted 4 months after the SARS outbreak. | IgG-ELISA against SARS-CoV. | Factors with p<0.1 in univariate analyzed in multivariate logistic regression with forward-stepwise procedure. Adjusted for age, gender, marital status, educational level, professional title and department. | Excluded 88 HCWs (10%) who were not on duty during the survey. 90 of 112 (80.4%) HCWs who were cases according to the MoH SARS definition and were on duty during the suvey were successfully interviewed.  | Wearing multi-layered cotton masks not associated with protection from SARS infection. | University hospitals not necessarily representative. Case definitions by clinical symptoms and serology discordant. Existence of concomitant interventions. |
| **Lau 2004(9)****Location**:5 hospitals of the New Territories East cluster in Hong Kong**SARS outbreak**: March 20-May 25, 2003 | N95 respirator and surgical mask. | All HCWs who worked in SARS wards and were registered as SARS cases by the Department of Health's eSARS registry and hospitalized; 48 medical and nursing staff and 24 assistants).(n=72) | HCWs working in the same ward, in the same job position and in proximity of the case-patient before he became ill. Did not show influenza-like or SARS-related symptoms during the study and were not identified as suspected SARS cases as of August 15, 2003.114 nominated by cases, 57 of which filled out the questionnaire. 30 HCWs plus 57 replacement HCWs for named controls who did not fill out the questionnaire randomly selected from the duty roster of the day before the case felt unwell, matching for job position.(n=143) | Self-administered (medical and nursing staff) or infection control nurse-administered (other staff) structured questionnaire. Asking frequency of using different types of respirtaory protection while having1. direct contact with SARS patients;2. contact with SARS or non-SARS patients;3. no patient contact.Participants were also asked whether masks fitted well and about frequency of touching mask. Quastionnaire administered within one week. | Probable cases: WHO definition.Suspected cases: did not completely fulfill the WHO definition but considered to be likely cases on the basis of clinical judgment. Laboratory confirmation by one or more of the following: RT-PCR; culture from throat wash, urine, stool and nasal swab specimens taken at days 1, 3, and 5; paired serologic assay from clotted blood taken at day 1 and 21.No blood test conducted among controls to determine whether they were asymptomatic SARS cases. | Use of respiratory protection coded into 2 categories: “never or occasionally" or “used most or all of the time”. Multivariate conditional logistic regression fitted using a forward-stepwise procedure with all variables that had p<0.10 in univariate analysis. Outcome: matched odds ratios and exact 95% CIs. | 72 of 77 probable and suspected SARS cases (93.5%) participated. 1 of 144 controls later became a suspected case. | Breakthrough transmission likely responsible for SARS infections, since N95 and masks were used consistently by almost all cases. Respiratory PPE alone not sufficient to eliminate SARS transmissionamong HCWs. | Recall bias, although exposure assessed within a week. |
| **Liu 2009(10)Journal:** Trop Med & Intern Health**Location**: Armed Forces Hospital hospital in Beijing**SARS outbreak**: March 5 - May 17, 2003 | Disposable, surgical,12- or 16-layer cotton mask, N95, and higher-level protective respirator. | HCWs diagnosed as probable SARS cases admitted to the hospital during the study period.(n=51) | HCWs working in the same hospital who had self-reported close exposure to a SARS patient (according to WHO criteria: 1m physical proximity), but were not diagnosed with SARS.(n=426) | Interviews with cases and controls by pre-tested questionnaire between June and July 2003. | WHO definition for probable SARS cases; all cases and controls confirmed by IgG-ELISA against SARS-CoV. | Univariate and multivariate logistic regression using stepwise-forward procedure with all variables with p-value< 0.1 in univariate analyses; statistical tests based on two-tailed probability. | Questionnaires filled out by 51⁄67 of all infectedsurvived staff in the hospital (76%);426 controls = 90% of all HCWs exposed to SARS. | Wearing masks is important to prevent infection. Both 16-layer and 12-layer cotton surgical masks, but not N95 or disposable masks, were highly effective.Two or more layers of masks are more protective than a single layer.The effect of protective measures can be enhanced through training. Compliance may not always be adequate when dealing with SARS patients. | Recall bias (although the study was conducted shortly after the outbreak and ORs were relatively high).Cases attributed their infection to some high risky performance and less efficient protection (wearing 1 layer of mask while attending patients), while the control group did the opposite.Number of N95 users was not large enough to give a significant p-value, which may have led to failure to detect an effect. |
| **Ma 2004(11)Journal:** Chin J Epidemiol**Location**: Mainland China**SARS outbreak**: 2003 | ≤12- or ≥16 layers cotton mask, single-use mask, N95 and pig-mouth style mask. | Medical personnel from 5 hospitals who were diagnosed with SARS. (n=47) | Medical personnel from the same department as cases working in the same period of time, who were not diagnosed with SARS.(n=426) | Standardized questionnaire with 49 questions administered by trained researchers. | SARS according to Chinese MoH definition. | χ2-test for univariate analysis. For variables that are statistically significant, multivariate logistic regression analysis. | Unknown | HCWs are recommended to use adequate masks, eye-protection and protective gowns during the process of clinical diagnosis and treatment of SARS patients. | 1:10 case to control ratio.  |
| **Nishiura 2005(12)Journal:** Am J Trop Med Hyg**Location**: Hanoi FrenchHospital (56-beds), Vietnam**SARS outbreak**: February 26 - April 7, 2003 | Surgical mask. | HCWs with laboratory-confirmed SARS; 28 hospital employees (3 doctors, 13 nurses and nursing assistants, 10 radiologists and other co-medical workers, and 2 administrative staff) and 1 relative of a patient. (n=29) | Vietnamese HCWs >20 years employed in the hospital, who had contact with confirmed cases or were exposed to patients’ relatives; 57 hospital employees (13 doctors, 20 nurses and nursing assistants, 13 radiologists and other co-medical workers, 11 receptionists and administrative staffs) and 41 relatives of patients.(n=98) | Exposures investigated in two phases: Stage 1: February26–March 4, from admission of index case to the onset ofsecondary cases;Stages 2 and 3: from suspicion of nosocomial spread (March 5) to local eradication in mid-March.Standardizedquestionnaires requiring one of two possible answers for each precaution (“performed” or “not performed”) followed by identicalconfirmation survey. | Laboratory-confirmed SARS by ELISA. | Univariate: χ2 or Fisher’s exact test. stage1: multivariate logistic regression (forward stepwise selection).Stages 2/3: restricted to 1) those with probable contacts2) those developing symptoms whose incubation period was within the greater than 95% CI of having occurred after the beginning of Stage 2 3) doctors and nurses;All variables significant in univariate analyses entered in final model. | 25/29 or 4/29 laboratory-confirmedSARS cases responded in phase 1 and phase 2/3, respectively; 90/98 or 26/98 controls responded in phase 1 and phase 2/3, respectively.  | The use of masks was significantly associated with the prevention of SARS transmission, although it did not reduce the reproduction number below 0 in a simulation model, i.e. it would be insufficient to contain an epidemic. | Selection bias (non-matched design);Recall bias (exposure has a strong intuitive causal link with outcome); potential random misclassification, as records completed 1 year after the outbreak; frequent use of masks among controls may have reduced the effect;unknown external confounding factors (e.g. reduced frequency of contacts and quarantine);simplicity of model (e.g. differential human susceptibility, variance in severity and prognosis, heterogeneous SARS transmssion);estimates of coverage may be biased, because taken from a non-representative sample (case-control design). |
| **Seto 2005(13)Journal:** Lancet**Location**: 5 hospitals in Hong Kong**SARS outbreak**: 2003 | Paper mask, surgical mask, or N95. | HCWs with documented exposures (patient care within 0.91m of an index patient with SARS symptoms) to 11 SARS index patients, who acquired SARS 2–7 days after exposure and had no exposure outside the hospital. (n=13)  | Uninfected HCWs with the same exposure characteristics.(n=241)  | Questionnaire to all staff in clinical regions caring for index patients between 15-24 March, 2003. | Fever ≥38° C, radiologicalinfiltrates compatible with pneumonia, and two of: chills,new cough, malaise, and signs of consolidation;sera from infected hospital staff tested by IFA. | χ2 or Fisher’s exact test for univariate analysis and forward stepwise selection for multivariable logistic regression. | 13 of 13 infected staff responded (100%);questionnaire distributed to all uninfected staff. | Surgical masks and N95, but not paper masks, were effective in reducing the risk of infection significantly. Only mask usage was significant in stepwise logistic regression, indicating that masks may be essential to protect HCWs. This, together with the finding that 30% of non-infected staff did not use masks, supports that in hospitals infection is transmitted by droplets rather than airborne. | Recall bias |
| **Teleman 2004(14)Journal:** Epidemiol Infect**Location**: Tan Tock Seng Hospital, Singapore**SARS outbreak**: March 1-22, 2003 | N95. | HCWs with probable SARS admitted between March 1 and March 31, 2003.(n=36) | Healthy HCWs working inSARS-affected wards during the same period, who reported exposure (<1m) to a patient subsequently confirmed with SARS. (n=50) | Telephone interviews with closed questionnaire at the time of the outbreak. | WHO definition, confirmed by serology. | χ2 or Fisher’s exact test for univariate analysis. Multivariate forward logistic regression including factors found significant in univariate analysis.Potential confounders selected among variables with p-values<0.2 in univariate analysis. | Interviewed 36 of 44 cases generated by source patients (83%); 6 too ill, 2 died before the interview;50 controls selected from the same wards, all were interviewed. | N95 is strongly protective against SARS infection. | No adjustment for superspreaders or for decrease in infectiousness over successive generations of cases.All exposures treated as equivalent, regardless of timing within the outbreak or source of infection.Precise exposure history not available.Viral load measurements not available for any patient (may explain wide range of infectiousness). Data on times of first and last exposure incomplete.Potential recall bias, although the study was contemporaneous with the outbreak, serology was available and ORs were large. |
| **Yin 2004(15)Journal:** Chin J Epidemiol**Location**: Guangdong, China**SARS outbreak**: 2003 | ≥12 layers S mask or disposable mask.  | SARS-infected HCWs from 10 major hospitals, who accessed the isolation units and/or participated in direct first aid for SARS patients. (n=77) | HCWs who were not infected with SARS.(n=180)  | Research team handed out questionnaire to HCWs to fill in on the spot. | Chinese MOH’s criteria from May 3, 2003. | χ2 test or Fisher’s exact test for univariate analysis; logistic regression with forward stepwise selection (Waldesian). | Questionnaire filled in on the spot by 77 cases and 180 controls, but unclear whether all possible cases enrolled. | SARS nosocomial infection can be prevented effectively through droplet and contact precautions. HCWs should comply to WHO and Chinese MOH regulations. |  |

Table S5. Summary of retrospective cohort studies assessing the effectiveness of masks and respirators against SARS infection (n=4)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Masks** | **Cohort** | **Ascertainment of exposure (mask use)** | **Assessment of outcome** | **Analysis Methods** | **Follow-up period** | **Main conclusions** | **Limitations** |
| **Loeb 2004(16)****Journal:** EID**Location:** Two critical care units in a 256-bed community hospital in Toronto, Canada**SARS outbreak:** March 8–April 3, 2003 (ICU) and March14–26, 2003 (CCU) | Surgical mask; N95. | Nurses who worked at least one shift while SARS-patients were present and entered patient’s room.(n=32)  | Standardized data collection form to extract information about patient care activities, corroborated by subsequent interviews with nurses. | Health Canada’s definitions for suspected and probable cases, in accordance with WHO's clinical case definitions; SARS seroprevalence confirmed by immunofluorescence. | Fischer’s exact two-sided tests. | For each nurse, from the first exposure to a source patient until 10 days (one incubation period) after the last exposure. | 80% reduction in risk of SARS-infection for nurses who consistently wear a N95 or surgical mask. If the entire cohort had used masks consistently, the risk of SARS would have been reduced from 6% to 1.4%. N95 may offer more protection than a surgical mask, but the small sample size may have prevented the study from detecting a significant effect. | Potential recall bias, although minimized by corroboration with medical records;small sample size. |
| **Nishiyama 2008(17)****Journal**:Jpn. J. Infect. Dis**Location:** Hanoi French Hospital, Vietnam**SARS outbreak**: March 3–17, 2003 | Mask. | Staff who had contact with SARS patients and did or did not subsequently develop SARS.(n=85) | Physician-administered interview. | Diagnosis according to WHO definition, confirmed by ELISA on serum samples drawn 6 months after the outbreak. | Multivariate logistic regression. | Exposure assessed retrospectively in October-November 2003 in 85/146 HCWs exposed to SARS at hospital A. | Compared to individuals wearing a mask, the risk of developing SARS was 12.6 times higher in individuals not using respiratory protection. |  |
| **Scales 2003(18)****Jounal:** EID**Location:** Mount Sinai Hospital, Toronto, Canada**SARS outbreak**: March 23, 2003 for ~31 hours | Surgical mask or N95. | Quarantined ICU staff who entered an undiagnosed index patient’s room. (n=31)HCWs present at the time of NPPV on a SARS patient.(n=22) | Interview with structured questionnaire. | SARS infection according to the WHO definition. | Fisher's exact test. | Follow-up for symptoms that developed during or after the quarantine period. 63 of 69 quarantined HCWs were interviewed (5 declined, 1 was not contacted). | The use of gowns, gloves and masks may reduce the risk of SARS transmission in some, but not all situations. | Small sample size, although exposure was well defined (less potential for confounding). |
| **Wilder-Smith 2005(19)****Journal:** EID**Location:** TTSH, Singapore**SARS outbreak**: from March 1, 2003 | N95. | HCWs who had contact with 3 SARS patients before mandatory infection control measures and consented to questionnaire and serologic test.(n=98) | Telephone interviews with closed questionnaire in April 2003. | ELISA on serum taken 8-10 weeks after exposure, confirmation by IFA and neutralization test.Penumonic SARS: sero-positive, fever, respiratory symptoms and pneumonic symptoms by radiology.Subclinical SARS: SARS-positive with fever and respiratory symptoms without radiologic changes.Asymptomatic SARS: SARS- positive without fever or respiratory symptoms. | Univariate analysis. | 98/105 consented to questionnaire, 80 of which also consented to serologic test. | Mask use was significantly more common in asymptomatic than pneumonic SARS patients. |  |

####  Pandemic H1N1 infection (pH1N1)

Table S6. Summary of matched case-control studies assessing the effectiveness of masks and respirators against pH1N1 infection (n=2)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Mask** | **Cases** | **Controls** | **Ascertainment of exposure** | **Assessment of outcome** | **Analysis Methods** | **Response rates** | **Main conclusions** | **Limitations** |
| **Zhang 2013(20)****Journal**: Influenza Other Respir Viruses**Location**: 25 hospitals in Beijing, China**H1N1 outbreak**: between August 30, 2009 and January 31, 2010 | N95, medical mask, cloth mask. | HCWs who i) worked full time in a high-risk setting;ii) had a ≤2m contact with a patient with a respiratory illness in the hospital; iii) confirmed pH1N1 diagnosis. (n=51) | 4 controls per case selected by simple randomization. Matched by hospital, ward, age (±5 years), and gender; i) worked full time; ii) exposed to patients with respiratory infections;iii) had neither ILI nor pH1N1 in the same period. (n=204) | Face-to-face survey during February 2010, using a structured questionnaire about the 7 days before symptom onset in cases and information about the same period from controls.  | pH1N1 cases reported to National Notifiable Infectious Disease Surveillance System during the outbreak; diagnosis confirmed by RT-PCR. | Univariate and multivariate conditional logistic regression analyses. Variables with p-value< 0.1 in univariate analysis were included into multivariate analysis. Backward logistic regression by removing variables with p-value> 0.1. | 2of 53 identified cases refused to participate; all 204 selected controls responded. | No evidence of a protective effect of masks against pH1N1. | Non-differential imperfect recall among cases or controls. Controls might be more likely to have forgotten about high-risk behaviors than cases.Small sample size.Serological tests not performed on controls, may lead to underestimated ORs.Matching procedure prevents analysis by type of occupational dutiesor type of ward. Factors outside hospital omitted. |
| **Deng 2010(21)Journal**: Chin J Prev Med**Location**: 25 hospitals in 11 areas in Beijing, China**H1N1 outbreak**: between August 30, 2009 and January 31, 2010 | High protection level mask. | HCWs i) working in a public hospital; ii) laboratory-confirmed pH1N1;iii) contact with pH1N1 patients.(n=54) | Matched to cases by hospital and department, age, etc.; no history and no symptoms of pH1N1 infection, i.e. fever, cough, sore throat, blocked nose or runny nose.(n= 216) | Face-to-face interview with questionnaires. | Laboratory-confirmed with pH1N1during the outbreak. | Univariate and multivariate logistic regression analysis.  | Response rate was 100%, but questionnaires for two cases and 8 corresponding controls were excluded.  | Using high protection level masks can protect HCWs from pH1N1 infection. | Small number of participants; matching of cases and controls by department will decrease the differences between the two groups as HCWs working in the same area are in frequent contact. |

Table S7. Summary of prospective cohort studies assessing the effectiveness of masks and respirators against pH1N1 infection (n=2)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Masks** | **Cohort** | **Ascertainment of exposure (mask use)** | **Assessment of outcome** | **Analysis Methods** | **Follow-up period** | **Main conclusions** | **Limitations** |
| **Cheng 2010(22)****Journal**: J Hosp Inf**Location**: Queen Mary Hospital, Hong Kong SAR**pH1N1 outbreak**: May 1 - August 8, 2009, when the first 100 laboratory-confirmed pH1N1 patients and 12 infected HCWs were identified | Surgical mask. | Asymptomatic subjects who had unprotected (≤1m contact with a confirmed case, both no surgical mask) or protected (at least one wearing a surgical mask) exposure to confirmed pH1N1 cases; 652 HCWs and 184 patients.(n=836) | Interview for compliance with infection control practices according to a standard questionnaire. | Daily monitoring of body temperature and URTI symptoms and laboratory confirmation by RT-PCR. | Fisher's exact test. | 7-day medical surveillance, including daily monitoring of body temperature and URTI symptoms by the ward-in-charge and infection control teams.Oseltamivir offered only if exposure to confirmed case was unprotected.Infections classified as community- or hospital-acquired. | Unclear. |  |
| **Jaeger 2011(23)****Journal**: ICHE**Location**: 2 hospitals and 1 outpatient clinic in Southern California, USA**pH1N1 outbreak**: from April 2009 onwards | Mask or N95. | HCWs exposed (<6 feet) to at least 1 of 6 laboratory-confirmed (RT-PCR) pH1N1 index patients, identified through review of medical records.(n=63) | Self-reported protective equipment use by type and frequency, assessed through standardized questionnaire; interviews conducted by hospital personnel between March 28 and April 22, 2009. | Paired serum samples collected 3-30 days post exposure and 13-32 days after baseline collection and tested by microneutralization and HI assays. Sero-conversion: ≥4-fold increase in titre by either assay; if late timing of baseline sample collection, samples achieving a microneutralization titer of ≥40 and a HI titer of ≥20 were considered seropositive. | Bivariate analysis with 2-sided Fisher's exact test. | 61/139 (44%) potentially exposed HCP unavailable or refused.78/139 (56%) completed initial questionnaires.76/139 (55%) provided followup data.72/139 (52%) contributed paired serum samples.9/72 (6%) excluded (had not been within 6 feet of an index patient).No data available on non-responders. | Nosocomial transmission was likely associated with inadequate use of personal protective equipment. | Low respone rate; low power prevented evaluating mask or N95 respirator use independently.Interviews conducted by hospital personnel, inhibiting complete disclosure of noncompliance with mask use.Causal, antecedent pH1N1 exposure not definitively determined. Potential transmission from asymptomatic or non-occupational contacts might be a source of infection.Extended postexposure period of 10 days may allow misclassificationof exposure.No data available on non-responders, systematic bias possible. |

Table S8. Summary of cross-sectional sero-epidemiologic studies assessing the effectiveness of masks and respirators against pH1N1 infection (n=2)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Masks** | **Population** | **Date of survey** | **Variables assessed** | **Survey methods** | **Analysis Methods** | **Response rate** | **Main conclusions** | **Limitations** |
| **Chokephaibulkit 2013(24)Journal:** Infl other Respir Viruses**Location**: Two large public hospitals in Bangkok, Thailand (3 ERs, 4 peediatric and 3 adult wards, 3 ICUs**pH1N1 outbreak**: June-August 2009  | N95 or surgical mask | Frontline HCWs during the outbreak (81.3% nurses and nurse assistants)(n=256); Subgroup analysis with nurses and nursing assistants.(n=198) | 1-19 October, 2009 (1 month after the end of the nosocomial outbreak). | Type and frequency of mask use and pH1N1 seroprevalence. | Random invitation to participate; anonymous self-administered questionnaire and simultaneous single blood draw for HI test (sero-positive=HI titer ≥40).  | Univariate analysis with binomial test. Multiple logistic regression of self-reported factors associated with a HI titer >40. | One third of HCWs in each ward invited, 97% of whichparticipated. | No evidence of a protective effect of masks against pH1N1. | Data is self-reported, but no verification of response accuracy.Small sample size. |
| **Toyokawa 2011(25)****Journal**: J Infect**Location**: Two general hospitals in Kobe, Japan**pH1N1 outbreak**: May 16 - June 5, 2009  | Surgical masks or N95. | Exposed nurses=nurses engaged in the care of a patient laterconfirmed to have pH1N1.(n=114) | June 18 - July 10, 2009, at least two weeks after the first pH1N1 epidemic had subsided. | Type and frequency of mask use and pH1N1 sero-prevalence. | Self-administered questionnaire and single blood draw for HI test (sero-positive=HI titer ≥1:40). | Logistic regression model analysis. | Overall response rate (268 participants, 176 of which nurses, 114 of which exposed): 81.5% and 83.8% in the two hospitals, respectively. Specific response rate for nurses not reported. | detectable trend towards sero-negativity for nurses consistently using surgical masks and N95, but no statistically significant association. |  |

Table S9. Summary of one ecologic study assessing the effectiveness of masks and respirators against pH1N1 infection

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Mask** | **Population** | **Exposure** | **Assessment of outcome** | **Analysis** | **Main conclusions** | **Limitations** |
| **Ang 2010(26)Journal**: CID**Location**: Tan Tock Seng hospital, Singapore**pH1N1 outbreak**: Period I: April 25 - June 18period II: June 19 - July 21period III: July 22 - August 31 | Period I: fit-tested N95 eye protection, gloves and gowns in ED and isolation facility;period II: universal use of surgical masks in all clinical areas, N95 in ED and isolation facility;period III: use of surgical masks for routine care of pH1N1 patients; use of N95 respirators only for aerosolizing procedures; surgical masks in ED and isolation facilities. | Hospital HCWs working during the pH1N1 pandemic who developed fever or ARI. | Hospital infection control measures implemented in each time period | ARI cases (cough, sore throat, or rhinorrhea) screened for pH1N1 by PCR on combined nasal and throat swabs. | Study reported proportion of confirmed pH1N1 cases among ARI cases during the three phases of the outbreak. | Surgical masks and N95 respirators do not appear to differ in efficacy in the prevention of the acquisition of pH1N1 by staff.pH1N1 infections among HCWs were most likely acquired through community exposure or in social settings with colleagues. | Absence of data on adherence to guidelines for personal protective equipment use; lack of serological data for exposed staff.  |

Table S10. Summary of a case series reporting the frequency of masks use among pH1N1 cases

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Mask** | **Population** | **Case definition** | **Ascertainment of exposure (mask use)** | **Main conclusions** | **Limitations** |
| **Wise 2011(27)****Journal**: Clin Infect Dis**Location**: 22 states in the USA**pH1N1 outbreak**: Case reporting: May 4 to June 1, 2009 (detailed reports only until May 15);illness onsets: Aprli 17 - May 26, 2009;case diagnosis: April 15 to June 1, 2009  | N95 and surgical masks (not reported separately). | pH1N1 cases among HCWs reported to the CDC (detailed exposure information obtained from 60 confirmed and 10 probable cases).(n=70)pH1N1 cases with probable or possible patient-to-HCW transmission among HCWs reported to the CDC:probable: <6 feet to patients with confirmed or probable pH1N1 infection without report of surgical mask or N95 use;possible: HCWs with either exposure to patients with known pH1N1 infection while using a surgical mask or N95 or exposure to patients with other respiratory illness regardless of respiratory protection use.(n=23) | Confirmed= ILI and positive RT-PCR or viral culture;probable= ILI and positive RT-PCR for influenza A, but negative RT-PCR for human H1 and H3.  | Case report form for each infected HCW filled out by health departments.  | Unclear. | Total number of infected HCWs was likely underreported.Case report forms not always completed, and data on certain infection control practices not collected.Failure to recall or recognize exposure to asymptomatic person: exposure misclassification possible.Case series only included those who developed pH1N1 infection, so no conclusions can be made about general use of personal protective equipment when caring for pH1N1 patients.Total number of HCWs at risk unknown. |

#### Other respiratory outcomes

Table S11. Summary of nested case-control study assessing the effectiveness of surgical masks against acute respiratory infection (ARI)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Mask** | **Cases** | **Controls** | **Ascertainment of exposure** | **Assessment of outcome** | **Analysis Methods** | **Response rates** | **Main conclusions** | **Limitations** |
| **Al-Asmary 2007(28)Journa**l: IJID**Location**: Al-Hada and Taif Military Hospitals, Saudi Arabia**Time period**: 2005 Hajj period  | Surgical facemasks. | Hajj medical mission personnel who developed ARI during Haij or within 2 weeks of return; 50% of participants is not medical staff.(n=64) | Hajj medical mission personnel who did not develop ARI during Haij or within 2 weeks of return.(n=186) | Self-administered questionnaire 2 weeks after Haij. | ARI cases detected through review of medical records.ARI= fever, headache or myalgia plus at least one of the following: coryza, sneezing, throat pain, cough with/without sputum and difficulty breathing.  | χ2-test and logistic regression. | Main cohort = all Hajj mission members of the 2 hospitals in 2005; (n= 375)Excluded= subjects with COPD and bronchial asthma or those who did not complete one week working for the mission; (n= 28) Response rate = 250/347 (72.0%) Specific response rate among cases or controls not stated.  | Mask users were not significantly protected against ARI compared to non-users.N95 masks should be considered for evaluation in the Hajj context. | Small number of subjects.Incomplete analysis of habits related to respiratory facemask use, such as frequency of mask changing and covering of the face by women during hospital work.  |

Table S12. Summary of cross-sectional surveys assessing the effectiveness of masks against CRI or ILI (n=2)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Masks** | **Population** | **Date of survey** | **Variables assessed** | **Survey methods** | **Analysis Methods** | **Response rate** | **Main conclusions** | **Limitations** |
| **Ng 2009(29)Journa**l: ICHE**Location**: different medical department in the 1,350-bed Prince of Wales general Hospital, Hong Kong SAR**Time period**: January 1- April 30, 2007 (flu season) | Face shield. | Medical ward nurses on duty during the flu season. (n=133) | Frst 2 weeks of May, 2007. | ILI symptoms (fever with >38°C and a cough and/or sore throat) and adherence to standard and/or droplet precautions during the care of patients with respiratory infection. | Anonymous, self-administered, closed-question questionnaire. | χ2-test for univariate comparisons and multivariate backward, stepwise logistic regression model.  | Response rate: 68.6% (133/194); no assessment of characteristics of non-respondents. Nurses on long sick or maternity leave were excluded. | Failure to comply with precautions is associated with an increased risk of developing ILI symptoms. | Questionnaire was anonymous and self-administered. |
| **Yang 2011(30)Journal**: Braz J Infect Dis**Location**: 8 hospitals in Beijing, China**Time period**: November 2007 - February 2008 (flu season) | Washable, reusable cotton-yarn mask and medical masks. | HCWs from departments with high or low risk of respiratory infection (respiratory,emergency, infectious disease and surgical).(n=400) | 20 April - 15 May, 2008. | Mask types and adherence to mask wearing:good: ≥70% of patient-contact timepoor: <70% of patient-contact time).CRI (at least two of the following symptoms simultaneously: fever, cough, sore throat, nasal congestion or rhinorrhea).  | Two-stage random sampling (sampling of 8 of 23 level 2 or 3 hospitals in Beijing and random enrollment of 50 HCWs per hospital). Face to face interview using a standardized questionnaire. | Univariate analysis; clinically significant factors or factors with p-values <0.5 included into multivariate logistic regression analyses. Backward logistic regression by removing variables with p > 0.1. | 400 of 400 HCWs selected participated and completed the study. | Masks protect HCWs from respiratory infection; the protective efficacy of medical masks is better than that of cotton yarn masks. | Recall bias from self-reporting.Whether infections occurred within or outside the hospital difficult to ascertain. |

 Additional results tables for observational studies

### Effectiveness of masks and respirators against pandemic H1N1 (pH1N1) infection (n=8)

Table S13. Matched case-control studies assessing the association of pH1N1 infection and mask use (n=2)

Odds ratios (ORs) for wearing masks among cases or controls using “wearing no mask” as reference category, unless otherwise stated

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Cases** | **Controls** | **Mask** | **% among** | **Unadjusted** | **Adjusted** |
| **Cases** | **Controls** | **OR** | **95% CI** | **p-value\*** | **OR** | **95% CI** | **p-value** |
| **Deng 2010**(21) | HCWs i) working in a public hospital ii) laboratory-confirmed pH1N1iii) contact with pH1N1 patients(n= 54)  | HCWs matched to hospital, department, age, etc; i) no history of pH1N1 infection ii) no symptoms of pH1N1 infection (n=216) | **High protection** level mask | 18·5(10/54) | 40·7(88/216) | 0·33 | 0·14–0·71 | 0·002 | 0·05  | 0·01–0·35 | 0·003 |
|  | **Frequency of mask use** |  |  |
| **Lengthened period** of mask useref: shorter period | 61·1(33/54) | 74·5(161/216) | 0·54 | 0·28–1·07 | 0·050 |  |
| **Zhang 2013**(20) | HCWs who i) worked full time in a high-risk setting ii) had a <2m contact with a patient with respiratory illness iii) diagnosed with pH1N1 by RT-PCR (n=51) | HCWs matched 4:1 with cases by hospital, ward, age and gender; i) worked full time ii) exposed to patients with respiratory infections iii) neither ILI nor confirmed pH1N1 in the same period (n=204) | **N95**# | 60·0(3/5) | 56·5(13/23) | 1·15 | 0·11–16·24 | 1·000 |  |  | 0·796 |
| **Medical**# | 94·9(37/39)  | 93·6(146/156) | 1·27 | 0·25–12·37 | 1·000 |  |  |  |
| **Cloth**# | 81·8(9/11) | 77·8(35/45) | 1·29 | 0·21–14·07 | 1·000 |  |  |  |
| **Any ≥2 masks/ day**ref: <2 masks/day  | 64·7(33/51) | 67·7(138/204) | 0·88 | 0·44–1·78 | 0·689 |  |  | 0·798 |
| **Frequency of mask use**  |  |  |  | 0·344 |
| **Often** (any mask)ref: seldom or never | 84·6(11/13) | 85·5(59/69) | 0·93 | 0·16–9·91 | 1·000 |  |  |  |
| **Always** (any mask)ref: seldom or never | 94·3(33/35) | 92·3(119/129) | 1·39 | 0·27–13·60 | 1·000 |  |  |  |
| **Only during HRP** (any mask)ref: seldom or never | 71·4(5/7) | 61·5(16/26) | 1·56 | 0·20–19·15 | 1·000 |  |  |  |

\* for χ2-test or Fisher’s exact test (for values <5)

RT-PCR= real-time reverse transcriptase-polymerase chain reaction

ILI= influenza-like illness

#worn ≥80% of time

HRP= high-risk procedure

Ref= reference category for OR

**Table S14. Prospective cohort studies assessing the risk of pH1N1 infection among HCWs according to mask wearing habits (n=2)**

Risk Ratios (RRs) for pH1N1 infection HCWs with different mask wearing habits.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Cohort** | **Primary outcome** | **Mask** | **% pH1N1-positives** **among HCWs wearing**  | **RR** | **95% CI** | **p-value\*** |
| **Mask**  | **No mask** |
| **Cheng 2010**(22) | Asymptomatic subjects who had unprotected (≤1m, both no surgical mask) or protected (at least one wearing a surgical mask) contact with a confirmed pH1N1 case; 652 HCWs and 184 patients·(n=836) | Risk of laboratory-confirmed pH1N1 infection among HCWs wearing or not wearing a mask during patient contactref: pH1N1-negative | **Surgical**  | 0·0(0/568) | 1·5(4/268) | n·a· |  |  |
| Risk of laboratory-confirmed pH1N1 infection among HCWs exposed to a patient wearing or not wearing a maskref: pH1N1-negative  | **% pH1N1-positives among HCWs exposed to a patient wearing**  |  |
| **Mask**  | **No mask** |
| 0·0(0/532) | 1·3(4/304) | n·a· |  |  |
| **Jaeger 2011**(23) | HCWs exposed (<6 feet) to at least 1 laboratory-confirmed pH1N1 index patient(n=63) | Risk of sero-conversion£ among HCWs wearing or not wearing a mask or N95 ref: no sero-conversion | **Mask** or **N95** | **% sero-conversions** **among HCWs wearing**  | **RR** | **95% CI** | **p-value\*** |
| **Mask** | **No mask** |
| 0·0(0/20) | 20·9(9/43) | n·a· |  |  |
| Risk of sero-conversion£ among HCWs wearing a mask or N95 100% or <100% of the time ref: no sero-conversion | **Mask** or **N95** | **% sero-conversions among HCWs wearing a mask** |  |
| **100%** of time | **<100%** of time |
| 0(0/12) | 17·6(9/51) | n·a· |  |  |

\* for χ2-test or Fisher’s exact test (for values <5)

Ref= reference category for RR

£ ≥4-fold increase in titre by either microneutralization or haemagglutination inhibition assay; if late timing of baseline sample collection, samples achieving a microneutralization titer of at least 40 and a haemagglutination inhibition titer of at least 20 were considered seropositive

Table S15. Cross-sectional sero-epidemiologic studies assessing the association of pH1N1 infection and mask use (n=2)

Odds ratios (ORs) for sero-positivity to pH1N1 among HCWs with different mask wearing habits, using “sero-negative” as reference category, unless otherwise stated

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Study population** | **Primary outcome** | **Mask** | **% sero-positive****among HCWs wearing** | **OR** | **95% CI** | **p-value**\* |
| **Mask**  | **No mask** |
| **Chokephaibulkit 2013**(24) | Frontline HCWs working during the peak of the first nosocomial pH1N1 outbreak(n=256) | Odds of being sero-positive among HCWs wearing or not wearing a mask | **Surgical** or **N95** | 12·6(30/239) | 17·6(3/17) | 0·67 | 0·17–3·85 | 0·467 |
| **N95** | 11·3(16/142) | 17·6(3/17) | 0·59 | 0·14–3·57 | 0·432 |
| **Surgical**  | 12·8(10/78) | 17·6(3/17) | 0·69 | 0·15–4·39 | 0·697 |
| Odds of being sero-positive among HCWs wearing a N95 respirator or a surgical mask | **N95** | **% sero-positive****among HCWs wearing** |  |
| **N95** | **Surgical**  |
| 11·3(16/142) | 12·8(10/78) | 0·86 | 0·35–2·25 | 0·733 |
| Odds of being sero-positive among HCWs wearing a mask >90-100% or <60% of the time during exposure events | **Surgical** or **N95** | **% sero-positive among** **HCWs wearing mask** |  |
| **>90–100%** of time | **<60%** of time |
| 13·3(24/180) | 0·0(0/8) | n·a |  |  |
| Odds of being sero-positive among HCWs wearing a mask 70-90% or <60% of the time during exposure events | **70–90%** of time | **<60%** of time |  |
| 14·3(8/56) | 0·0(0/8)  | n·a· |  |  |
| Subgroup of nurses and nursing assistants within the main cohort(n=198) | Odds of being sero-positive among nurses wearing or not wearing a mask  | **Surgical** or **N95** | **% sero-positive****among nurses wearing** |  |
| **Mask**  | **No mask** |
|  |  | 0·43 | 0·18–1·11  | 0·039 |
| **Toyokawa 2011**(25) | Nurses engaged in the care of a patient later confirmed to have pH1N1(n=114) | Odds of sero-conversion among nurses always wearing a mask or nurses intermittently or neverwearing a maskref: no sero-conversion |  | **% sero-conversions among** **HCWs wearing mask** |  |
| **Always** | **Intermittently** or **never** |  |
| **Surgical** (ED) | 4·8(4/83) | 25·0(1/4) | 0·15 | 0·01–9·95 |  0·214 |
| **N95** (ED) | 5·2(4/77) | 10·0(1/10) | 0·49 | 0·04–26·95 | 0·465 |
| **N95** (IW) | 4·9(3/61) | 0·0(0/3) | n·a·  |   |   |

\* for χ2-test or Fisher’s exact test (for values <5)

ED= emergency department

IW= isolated ward

Ref= reference category for OR

**Table S16. Ecologic study assessing the risk of pH1N1 infection among HCWs according to mask wearing habits (n=1)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Study population** | **Primary outcome** | **Mask**  | **Nr of ARI cases** | **Nr pH1N1 cases** | **% pH1N1 cases** |
| **Ang 2010**(26) | Hospital HCWs working during the pH1N1 pandemic in 2009 who developed fever or ARI | Prevalence of laboratory-confirmed pH1N1 cases among ARI cases in different time periods:I. no local transmissionII. local transmissionIII. continued local transmission | I. **Fit-tested N95**, eye protection, gloves, and gowns in ED and isolation facility | 573 | 0 | 0 |
| II.Universal use of **surgical masks** in all clinical areas, **N95** in ED and isolation facility | 1065 | 33 | 3·1 |
| III.Use of **surgical masks** for routine care of pH1N1 patients; use of **N95** respirators only for aerosolizing procedures; **surgical masks** in ED and isolation facilities | 955 | 15 | 1·6 |

ARI= acute respiratory illness

ED= emergency department

Table S17. Mask wearing habits in a case series of pH1N1-infected HCWs (n=1)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Study population** | **Primary outcome** | **Mask** | **Always**  | **Inconsistently** | **Most of the time**  | **Sometimes**  | **Never** |
| **Wise 2011**(27) | pH1N1 cases among HCWs from hospitals and outpatients clinics reported to the CDC Confirmed: n=60Probable: n=10(n=70) | Frequency (%) of mask use while caring for pH1N1 patients  | **N95** and/or **surgical mask** |  4·3(3/70) |  12·9(9/70) |  |  |  |
| pH1N1 cases among HCWs with probable or possible patient to-HCW transmission(n=23) | Frequency (%) of mask use during interaction with presumed source | **Surgical** (n=19) | 15·8(3/19) |  | 10·6(2/19) | 26·3(5/19) | 47·3(9/19) |
| **N95** (n=20) | 10·0(2/20) |  | 0·0(0/20) | 20·0(4/20) | 70·0(14/20) |

CDC= Centers for Disease Control and Prevention

ARI=acute respiratpry infection

### Effectiveness of masks and respirators against other respiratory outcomes (n=3)

Table S18. Nested case-control study assessing the association of acute respiratory infection (ARI) with frequency of surgical mask use

Odds Ratios (ORs) for always or intermittently wearing a mask among cases or controls using “never wearing a mask” as reference category.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Cases** | **Controls** | **Frequency of surgical****mask use** | **% among** | **Unadjusted** | **Adjusted** |
| **Cases** | **Controls** | **OR** | **95% CI** | **p-value\*** | **OR** | **95% CI** | **p-value** |
| **Al-Asmary 2007**(28) | Hajj medical mission personnel who developed ARI symptoms during Haij or within 2 weeks of return (n=64) | Hajj medical mission personnel who did not develop ARI symptoms during Haij or within 2 weeks of return (n=186) | **Always** | 81·8(18/22) | 86·8(92/106) | 0·68 | 0·19–3·20 | 0·512 | n·a· |  |  |
| **Intermittent**  | 91·3(42/46) | 85·1(80/94) | 1·84 | 0·53–8·12 | 0·423 |  |  |  |

\* for Fisher’s exact test

Table S19. Cross-sectional survey assessing the prevalence of influenza-like illness (ILI) among HCWs with different adherence to mask use

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Study population** | **Primary outcome** | **Mask**  | **% ILI-positives according to** **mask use adherence**  | **Unadjusted** | **Adjusted** |
| **Optimal** | **Sub-optimal** | **OR** | **95% CI** | **p-value**\* | **OR** | **95% CI** | **p-value** |
| **Ng 2009**(29) | Medical ward nurses on duty from January 1 to April 30, 2007 (n=133) | Odds ratios (ORs) for ILI prevalence among nurses with optimal or suboptimal adherence to face shield use during aerosol-generating procedureref: no ILI symptoms | **Face shield** | 10·8(10/93) | 50·0(20/40) | 0·12 | 0·44–0·32 | <0·001 | 0·28 | 0·09–0·85 | 0·024 |

\* for χ2-test

Table S20. Cross-sectional survey assessing the prevalence of clinical respiratory illness (CRI) among HCWs according to type and frequency of mask use

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Study population** | **Primary outcome** | **Mask**  | **% CRI-positive among HCWs** **using a medical mask** | **Unadjusted** | **Adjusted** |
| **≥70%** of time | **<70%** of time | **OR** | **95% CI** | **p-value**\* | **OR** | **95% CI** | **p-value** |
| **Yang 2011**(30) | HCWs from departments with high or low risk of respiratory infection(n=400) | Odds ratio (OR) for CRI prevalence among HCWs wearing a medical mask ≥70% or <70% of patient contact timeref: no CRI  | **Medical**  | 42·1(118/280) | 36·7(44/120) | 1·26 | 0·79–2·00 | 0·307 | 0·60 | 0·37–0·98 | 0·041 |
| Odds ratio (OR) for CRI prevalence among HCWs wearing a medical or cotton-yarn maskref: no CRI  | **Medical** (control: cotton-yarn) | **% CRI+ among HCWs using** | **Unadjusted** | **Adjusted** |
| **Medical** | **Cotton-Yarn** | **OR** | **95% CI** | **p-value**\* | **OR** | **95% CI** | **p-value** |
| 45·3(73/161) | 37·2(89/239) | 1·40 | 0·91–2·14 | 0·105 | 0·60 | 0·39–0·91 | 0·018 |

\* for χ2-test or Fisher’s exact test (for values <5)

Risk of bias in included observational studies

 Table S21. Risk of bias in observational studies assessing the effectiveness of masks and respirators against SARS

|  |  |
| --- | --- |
|  | **Newcastle Ottawa Scale score** |
| **Case control studies** | **Selection** | **Comparability** | **Exposure** |
| Chen 2009(8) | \*\*\*\* |  | \* |
| Lau 2004(9) | \*\*\*\* | \*\* | \* |
| Liu 2009(10) | \*\*\*\* | \*\* | \* |
| Ma 2004(11) | \*\*\* | \*\* | \* |
| Yin 2004(15) | \*\*\* | \*\* | \*\* |
| Seto 2003(13) | \*\*\*\* | \*\* | \*\* |
| Nishiura 2005(12) | \*\*\*\* | \*\* | \* |
| Teleman 2004(14) | \*\*\*\* | \*\* | \* |
| **Cohort studies** | **Selection** | **Comparability** | **Outcome** |
| Loeb 2004(16) | \*\*\*\* |  | \*\*\* |
| Nishiyama 2008(17) | \*\*\* | \*\* | \*\* |
| Scales 2003(18) | \*\*\*\* |  | \*\* |
| Wilder-Smith 2005(19) | \*\*\*\* |  | \*\*\* |

Table S22. Risk of bias in observational studies assessing the effectiveness of masks and respirators against pH1N1

|  |  |
| --- | --- |
|  | **Newcastle Ottawa Scale score** |
| **Case control studies** | **Selection** | **Comparability** | **Exposure** |
| Zhang 2012(20) | \*\*\*\* | \*\* | \*\* |
| Deng 2010(21) | \*\*\* | \*\* | \*\* |
| **Cohort studies** | **Selection** | **Comparability** | **Outcome** |
| Cheng 2010(22) | unclear | unclear | unclear |
| Jaeger 2011(23) | \*\*\*\* |  | \*\* |
| **Cross-sectional studies** | **Selection** | **Comparability** | **Outcome** |
| Chokephaibulkit 2013(24) | \*\* | \* | \*\*\* |
| Toyokawa 201(25) | \*\* |  | \*\*\* |
| **Other studies** |  |  |  |
| Ang 2010(26) | n.a | n.a | n.a |
| Wise 2011(27) | n.a | n.a | n.a |

Table S23. Risk of bias in observational studies assessing the effectiveness of masks and respirators against other respiratory outcomes

|  |  |
| --- | --- |
|  | **Newcastle Ottawa Scale score** |
| **Case control studies** | **Selection** | **Comparability** | **Exposure** |
| Al-Asmary 2007(28) | \*\*\* |  | \* |
| **Cross-sectional studies** | **Selection** | **Comparability** | **Outcome** |
| Ng 2009(29) | \*\*\* | \* | \* |
| Yang 2011(30) | \*\*\*\* | \* | \* |

PRISMA checklist

|  |  |  |  |
| --- | --- | --- | --- |
| **Section/topic** | **#** | **Checklist item** |  **Reported in** |
| **Title** |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | * Lines 1-2
 |
| **Abstract** |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | * Abstract
 |
| **Introduction** |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | * Lines 77-89
 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | * Lines 90-96
 |
| **Methods** |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | * Appendix C
 |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | * Lines 105-114
 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | * Lines 103-104
* Line 117
 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | * Appendix B, Tables S1 and S2
 |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis) | * Figure 1
* Lines 117-119
 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | * Lines 121-125
* Appendix B, Tables S3-S12
 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | * Lines 105-114
 |
| Risk of bias in individualstudies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | * Lines 127-131
 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | * Appendix B, Table 1
 |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis. | * Lines 133-137
* Lines 140-153
 |
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | * Lines 138-139
 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | n.a. |
| **Results** |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | * Lines 156-160
* Figure 1
 |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | * Appendix B, Tables S3-S12
 |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | RCTs: * Figure S1

Observational studies: * Appendix B, Tables S21-S23
* Figure 5
 |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | RCTs:* Appendix B, Table S3
* Lines 167- 188

Observational studies:* Lines 191-214
* Lines 229-251
* Appendix B, Tables 2-3
* Appendix B, Tables S4-S20
 |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | RCTs:* Lines 163- 188
* Figures 2-4
* Appendix B, Table 1

Observational:* Lines 214-228
* Figure 5
 |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | * Lines 159-160
* Figure S2
 |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | n.a. |
| **Discussion** |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | RCTs:* Lines 254-266

Observational:* Lines 277-295
 |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | RCTs:* Lines 267-275

RCTs and observational:* Lines 197-318

Meta-analysis of observational* Lines 320-329
 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | * Lines 332-369
 |
| **Funding** |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | * Line 372
 |

APPENDIX C: systematic review and meta-analysis protocol

1. Objective

To assess the protective effect of respiratory personal protective equipment, (rPPE) such as surgical facemasks and N95 respirators, against respiratory infections among healthcare workers (HCWs).

1. Criteria for literature search

The databases Pubmed, Web of Science and EMBASE are going to be searched for relevant articles according to pre-specified inclusion and exclusion criteria with no language or time restrictions.

Inclusion criteria

1. Study design: published randomized control trials and observational studies, e.g. case-control, cohort or cross-sectional studies;
2. Population: any professional category of HCW, e.g. doctors, nurses, surgeons and other personnel
3. Intervention: any type of rPPE worn by HCWs, e.g. surgical facemasks and N95 respirators;
4. Outcome: efficacy or effectiveness of different types of rPPE in reducing the risk of respiratory infection in the study population, e.g. seasonal and pandemic influenza, influenza-like illness, common cold, SARS, RSV, acute respiratory infection, upper respiratory tract infection and rhinovirus, adenovirus and coronavirus infection;
5. Settings: Any healthcare setting worldwide, e.g. hospital or nursing home.

Exclusion criteria

1. editorials, comments, letters and public press articles;
2. reviews and guidelines;
3. mathematical models and studies conducted in simulated environments;
4. ongoing studies and non peer-reviewed reports (e.g. conference abstracts, oral presentations and posters);
5. studies assessing the cumulative impact of several different interventions;
6. studies assessing mask effectiveness in protection from non-respiratory infections, e.g. surgical site infection or blood splashes;
7. studies where rPPE is only worn by patients, but not by HCWs.
8. Search terms

One search string is going to be constructed for each database including the following search terms:

Intervention

Mask\*, facemask\*, face mask, face masks, medical mask, medical masks, medical facemask, medical facemasks, medical face mask, medical face masks, surgical mask, surgical masks, surgical facemask, surgical facemasks, surgical face mask, surgical face masks, N95, N97, N99, FFP, FFP1, FFP2, FFP3, respirator, respirators, respiratory protection, respiratory protective device, respiratory protective devices, personal protective equipment, PPE, face protection, airborne precaution, airborne precautions, droplet precaution, droplet precautions, non-pharmaceutical intervention, non-pharmaceutical interventions.

Outcome

Infection\*, emerging infection, emerging infections, respiratory infection, respiratory infections, respiratory tract infection, respiratory tract infections, acute respiratory infection, acute respiratory infections, ARI, acute respiratory tract infection, acute respiratory tract infections, upper respiratory tract infection, upper respiratory tract infections, URTI, common cold, influenza, parainfluenza, flu, pandemic influenza, SARS, influenza-like illness, ILI, rhinovir\*, adenovir\*, coronavir\*, RSV, respiratory syncytial virus, respiratory syncytial viruses, infection control, communicable disease control, infectious disease transmission, communicable disease transmission, cross infection, cross infections, cross-infection, cross-infections, HCAI, healthcare-associated infection, healthcare-associated infections, health care-associated infection, health care-associated infections, health-care-associated infection, health-care-associated infections.

Population

HCW\*, healthcare worker, healthcare workers, health care worker, health care workers, health-care worker, health-care workers, healthcare professional, healthcare professionals, health care professional, health care professionals, health-care professional, health-care professionals, nurse\*, doctor\*, practicioner\*, practitioner\*, staff, healthcare personnel, health care personnel, health-care personnel.

1. Article selection

Two researchers will independently retrieve the relevant articles from the database output and a third researcher will be consulted in the case of disagreement.

1. Data extraction

For each study design, we will use a pre-specified electronic spreadsheet data extraction form. Data will be extracted from each article as follows:

Randomized controlled trials

Author, journal, country, study period, population, study design details, intervention(s), comparison group(s), primary and additional outcomes, follow-up details, analysis methods, results and limitations.

Case-control studies

Author, journal, location, study period, case population, control population, rPPE type(s) assessed, methods used to ascertain exposure and outcome, analysis methods, response rates, main results, conclusions and limitations.

Cohort studies

Author, journal, location, study period, cohort details, rPPE type(s) assessed, methods used to ascertain exposure and outcome, analysis methods, details of follow-up period, results, main conclusions and limitations.

Cross-sectional studies

Author, journal, location, study period, details of study population, rPPE type(s) assessed, date of survey, variables assessed, survey methods, analysis methods, response rate, results, main conclusions and limitations.

Other

Author, journal, location, study period, details of study population, rPPE type(s) assessed, methods used to ascertain exposures and outcomes, analysis methods, results, main conclusions and limitations.

1. Risk of bias in included studies

Two authors will independently assess the risk of bias and a third author will be consulted in case of disagreement.

Randomized controlled trials

The risk of bias in randomized controlled trials will be assessed using the Cochrane Risk of Bias tool.(1) Review Manager 5.3 will be used to create a visual summary of the quality assessment.

Observational studies

The risk of bias in observational case-control and cohort studies will be assessed using the Newcastle-Ottawa scale.(31) An adapted version(32) of the scale will be used to assess the risk of bias in cross-sectional studies.

1. Meta-analysis

The meta-analysis of randomized controlled trials and observational studies will be conducted separately. Within each group, eligible studies will be combined according to types of rPPE and outcomes assessed. Risk ratios and odds ratios will be used as summary effect estimates for randomized controlled trials and observational studies, respectively. Between-study heterogeneity will be assessed using the *I2* statistic and random-effects models will be used for meta-analyses with *I2*≥60% and p-value for heterogeneity <0.05. Factors affecting heterogeneity will be assessed by meta-regression. For each meta-analysis, individual and pooled effect estimates will be summarized in one forest plot. To identify potential publication bias, separate funnel plots will be created for randomized controlled trials and observational studies and the Harbord test of small-study effects will be used to assess funnel plot asymmetry. All statistical analyses will be performed with STATA IC version 12 (Stata Corporation). No patients will be involved in the completion of this article.

1. Deviations from pre-specified protocol

We conducted four meta-analyses of observational studies assessing the protective effect of different types of r PPE against SARS infection, using odds ratios as summary statistics. However, odds ratios may not be appropriate representatives of risk ratios when the baseline risk of infection is high,(33, 34) as was the case during the nosocomial SARS outbreaks investigated in these studies. To facilitate an appropriate interpretation of the findings from the meta-analyses of observational studies, we calculated the range of plausible risk ratios for each summary effect estimate, assuming baseline risks of SARS infection ranging from 20% to 60%, as estimated from the available cohort studies.(16, 18, 19) To allow comparability, the meta-analyses were performed with unadjusted effect estimates.

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