World Patient Safety Day 2020:

Sharing safe practices during the response to COVID-19

ASSESSMENT OF RISK FACTORS FOR COVID-19 IN HEALTH WORKERS: PROTOCOL FOR A CASE-CONTROL STUDY

Alessandro Cassini on behalf of the Infection Prevention and Control Technical and Clinical Hub

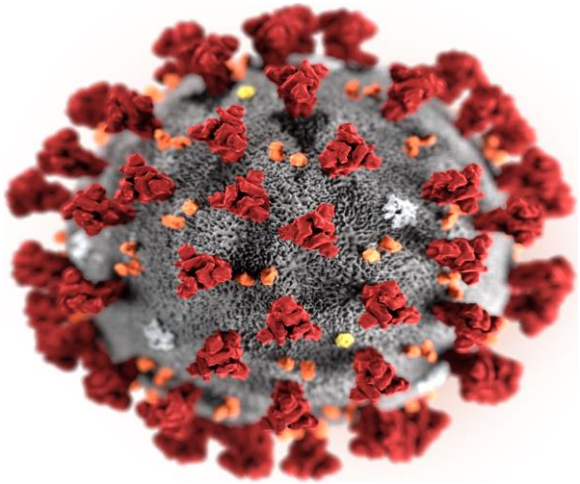
World Health Organization

World Health Organization

17 September 2020

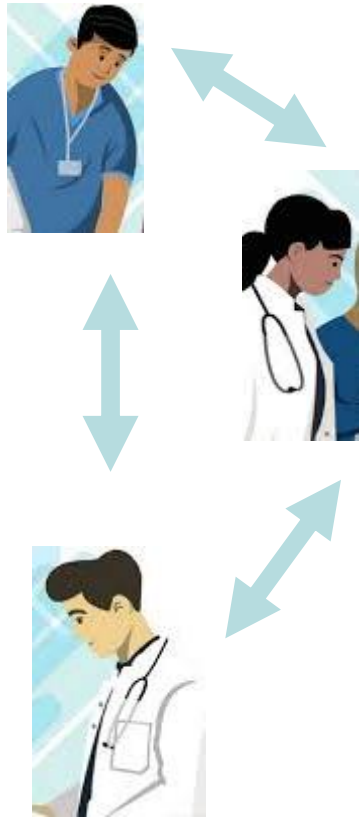
Impact of infections in health workers

- Potential further transmission:
  - within healthcare facilities to patients and other HW
  - to the community through their families
- Health system impact:
  - Infected HW isolation leads to health workforce depletion
    - in turn longer work hours for remaining staff
- Societal impact:
  - Possible mistrust from the community and under-utilization of essential health services



Transmission patterns of health workers

COVID patients



Community

Non COVID patients

- Assuming availability and adherence to PPE, risk of infections among health workers might depend primarily on **community circulation of the virus**

- Key Question 1. What is the **burden** of SARS-CoV-2, SARS-CoV-1, and MERS-CoV on **HCWs** and how do burdens vary according to age, sex, and presence of comorbidities?
- Key Question 2. What are the **risk factors for HCW infections** with SARS-CoV-2, SARS-CoV-1, and MERS-CoV?
- Key Question 3. What are the **risk factors for household transmission** of SARS-CoV-2, SARS-CoV-1, and MERS-CoV from HCWs?

Health burden of COVID-19 in health workers

- Netherlands: 6.4%; China: 3.8%, 5.1%
- Overall incidence of COVID-19 infection in HCWs was higher than that of the general population: **144.7 vs. 41.7 per 10^6 people (3.5 times more)**
- Incidence in HCWs increased in the same way compared to the general population
- However, less severe illness and mortality are observed among HWs
- Risk factors :
  - Female sex
  - Direct contact with cases
  - nurses

Chou R et al. Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers: A Living Rapid Review. Ann Intern Med. 2020;173(2):120-36.

Psychological burden of COVID-19 in health workers

- Mental health issues common in HWs:
  - 14% - 15% depression
  - 12% - 24% anxiety
  - 30% - 39% psychological distress
  - 8% - 60% sleep issues

➢ Highest burden is in nurses working in COVID-19 wards

Chou R et al. Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers: A Living Rapid Review. Ann Intern Med. 2020;173(2):120-36.

Risk factors for health workers infections

- Health workers have reported the following as risk factors:
  - Working in high risk departments (**ICU**) : RR 2.13
  - Suboptimal **hand washing** before and after patient contact: RR 3.10, 2.82
  - Longer work hours
  - Improper use of **PPE**: RR 2.82
  - Insufficient **education and training** on IPC; PPE and other measures
  - Certain exposures (e.g., involvement in intubations, direct patient contact, or contact with bodily secretions) were associated with increased infection risk
  - **Family member** with COVID-19: RR 2.76

Chou R et al. Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers: A Living Rapid Review. Ann Intern Med. 2020;173(2):120-36.

Conclusions of the rapid review

- Health care workers account for a **significant proportion** of coronavirus infections and may experience particularly high infection incidence after unprotected exposures.
- Illness severity was lower than in non-HCWs.
- **Depression, anxiety, and psychological distress** were common in HCWs during response to COVID-19.
- The strongest evidence was on **PPE** use and decreased infection risk.
- The association was most consistent for **masks** but was also observed for **gloves, gowns, eye protection, and handwashing**; evidence suggested a dose-response relationship. No study evaluated PPE reuse.
- Certain exposures (such as involvement in intubations, direct patient contact, or contact with bodily secretions) were associated with increased infection risk. Infection control **training** was associated with decreased risk.

Chou R et al. Epidemiology of and Risk Factors for Coronavirus Infection in Health Care Workers: A Living Rapid Review. Ann Intern Med. 2020;173(2):120-36.

International Council of Nurses (ICN)

May 2020, ICN:

- Calls for governments to report on HW infections
- Others have reported >90,000 HW infections and 260 nursing deaths
- ICN collects data from 30 countries: 6% HW infections (range from 0-18%)

International Council of Nurses
Consejo Internacional de Enfermeras
Conseil International des Infirmières

Press release 16 September 2020

- 1000 nurses died in 44 countries. 10% of total infections are in health workers: 3 million HWs
- Less than half of countries surveyed classified COVID-19 as an occupational disease
  - Reducing access to **compensation** and to equipment, training, testing, mental health support or financial support

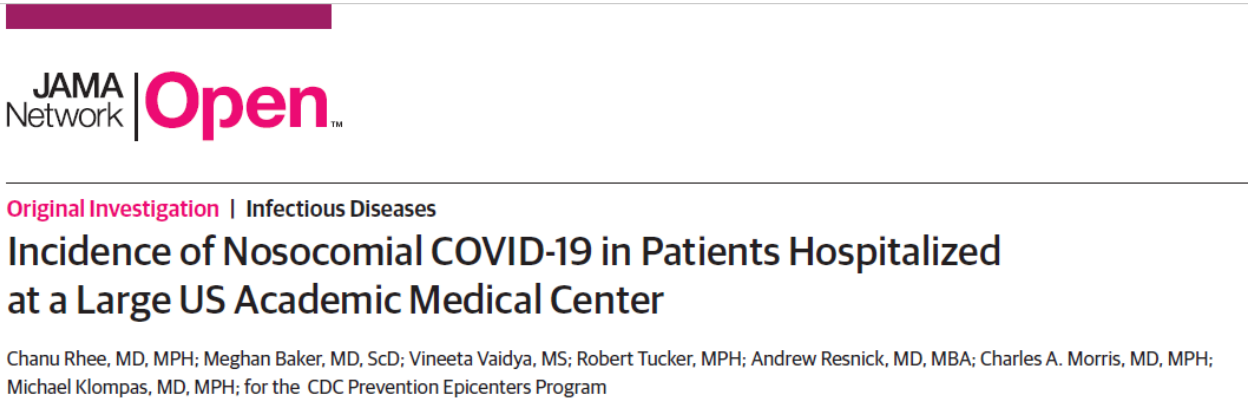
- ➢ Lack of data collection on infection rates
- ➢ Inadequate PPE, particularly in care homes
- ➢ Inadequate testing and IPC training
- ➢ Violence and discrimination against nurses
- ➢ Lack of mental health support

Evidence on impact of COVID-19 on HWs

- MMWR: HW status represents a subset of reported cases, 19% HWs
- Potential for exposure in multiple settings especially as community transmission increases
- Alberta report: HCW risk was 9-11 times higher than the general population, regardless of country/region risk status
- BJGP mortality in UK: HWs may have had greater exposure than the general population but have a relatively lower mortality
- BMJ: staff in contact with affected patients had greater levels of acute or post-traumatic stress (OR 1.71) and psychological distress (1.74)

CDC Covid-19 Response Team. Characteristics of Health Care Personnel with COVID-19 - United States, February 12-April 9, 2020. MMWR 2020;69(15):477-81.
https://www.albertahealthservices.ca/assets/info/ppih/if-ppih-covid-19-hcw-risk-rapid-review.pdf
Levene LS et al. COVID-19 cumulative mortality rates for frontline healthcare staff in England. Br J Gen Pract. 2020;70(696):327-8.
Kisely S et al. Occurrence, prevention, and management of the psychological effects of emerging virus outbreaks on healthcare workers: rapid review and meta-analysis. BMJ. 2020;369:m1642.

Nosocomial transmission is not inevitable


JAMA Network Open

Original Investigation | Infectious Diseases

Incidence of Nosocomial COVID-19 in Patients Hospitalized at a Large US Academic Medical Center

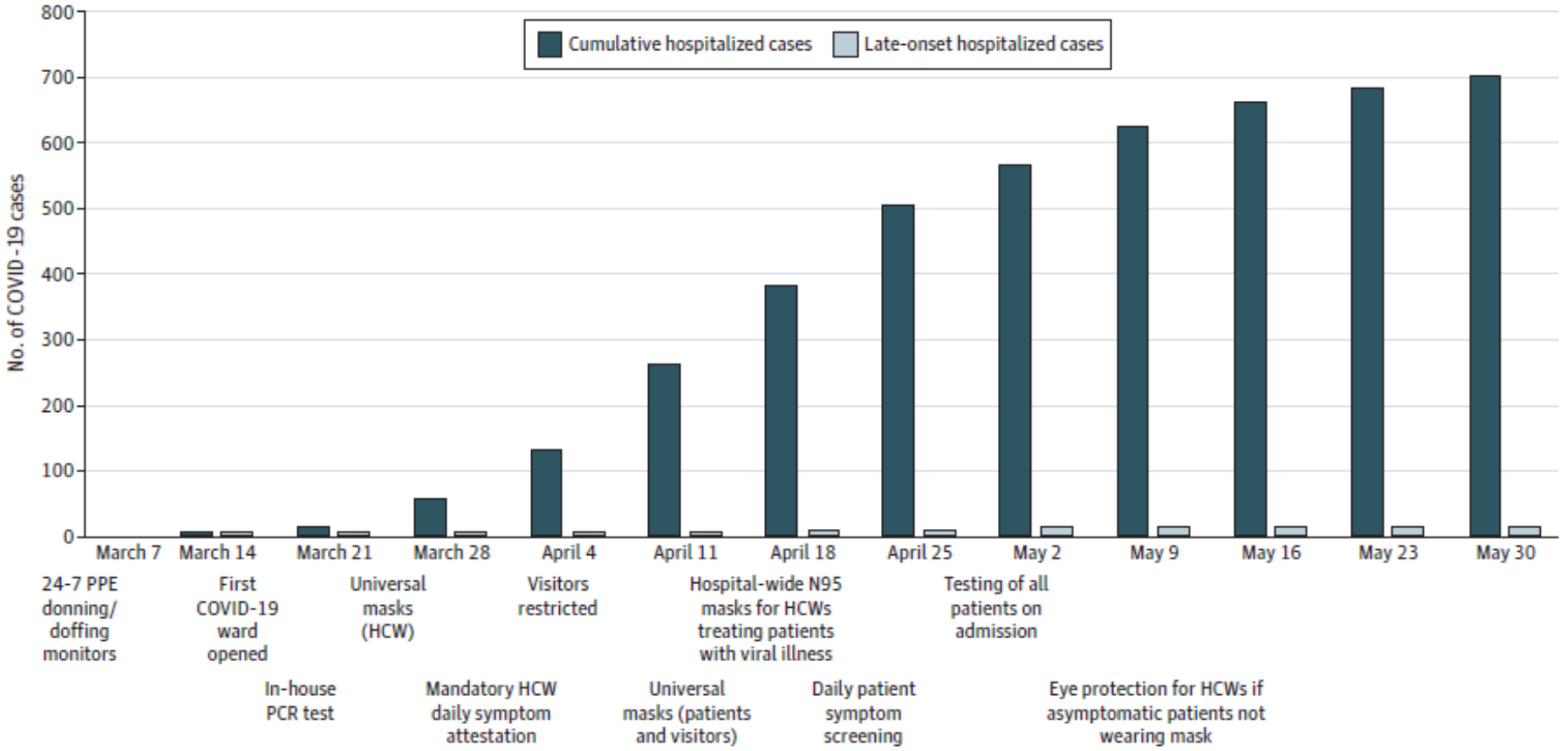
Chanu Rhee, MD, MPH; Meghan Baker, MD, ScD; Vineeta Vaidya, MS; Robert Tucker, MPH; Andrew Resnick, MD, MBA; Charles A. Morris, MD, MPH; Michael Klompas, MD, MPH; for the CDC Prevention Epicenters Program

- Based on 9149 patients admitted to a large US academic medical center over a 12-week period
- 697 were diagnosed with COVID-19
- Only 2 hospital-acquired cases were detected: 1 patient was likely infected by a pre-symptomatic spouse, other had no known exposures

➢ These findings suggest that robust and rigorous infection control practices may be associated with minimized risk of nosocomial spread of COVID-19 to hospitalized patients.

Rhee C, Baker M, Vaidya V, Tucker R, Resnick A, Morris CA, et al. Incidence of Nosocomial COVID-19 in Patients Hospitalized at a Large US Academic Medical Center. JAMA Netw Open. 2020;3(9):e2020498.

Figure. Cumulative Number of Total and Late-Onset Hospitalized Coronavirus Disease 2019 (COVID-19) Cases by Week and Associated With Infection Control Policies



Late-onset hospitalized COVID-19 cases were defined as patients who first tested positive for severe acute respiratory syndrome coronavirus 2 by reverse-transcription polymerase chain reaction (PCR) on hospital day 3 or later. Table 2 gives a detailed description of the major infection control policies and interventions. HCW indicates health care worker; PPE, personal protective equipment.

Rhee C, Baker M, Vaidya V, Tucker R, Resnick A, Morris CA, et al. Incidence of Nosocomial COVID-19 in Patients Hospitalized at a Large US Academic Medical Center. JAMA Netw Open. 2020;3(9):e2020498.

Barriers to health workers' adherence to IPC guidelines for respiratory infectious diseases:

- Local guidelines were too long and ambiguous or changing or of limited quality
- Increased workloads and fatigue; low level of support received from management
- Lack of IPC training and on COVID-19
- Insufficient space to isolate patients
- Lack of PPE and poor quality equipment
- Isolated patients felt frightened, stigmatized, etc

Components that were identified to have facilitated health workers' adherence

- Minimising overcrowding, fast-tracking infected patients, restricting visitors, and providing easy access to HH
- Clear communication about IPC guidelines
- Fear of infecting themselves or their families, or their patients
- When all staff (including admin, kitchen etc) implement IPC guidelines

Cochrane Library

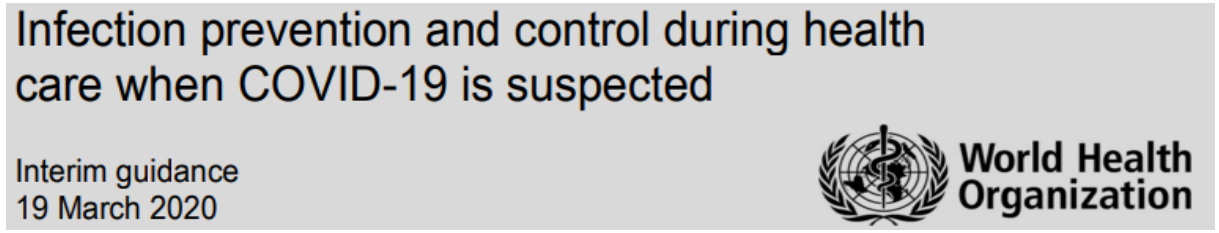
Cochrane Database of Systematic Reviews

Barriers and facilitators to healthcare workers' adherence with infection prevention and control (IPC) guidelines for respiratory infectious diseases: a rapid qualitative evidence synthesis (Review)

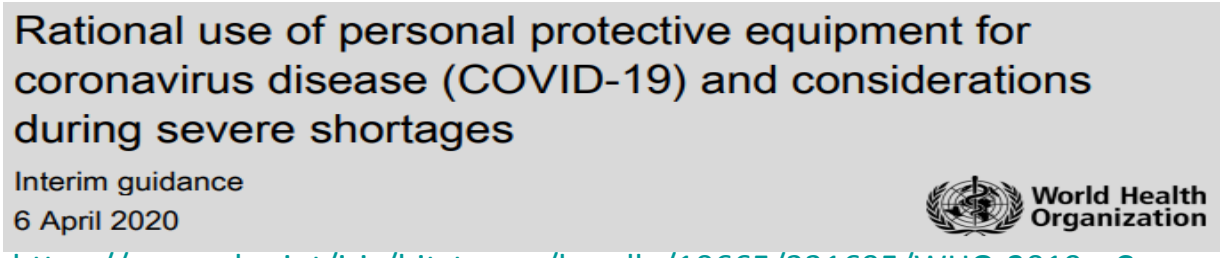
Houghton C, Meskell P, Delaney H, Smalle M, Glenton C, Booth A, Chan XHS, Devane D, Biesty LM

Houghton C et al. Barriers and facilitators to healthcare workers' adherence with infection prevention and control (IPC) guidelines for respiratory infectious diseases: a rapid qualitative evidence synthesis. Cochrane Database Syst Rev. 2020;4:CD013582.

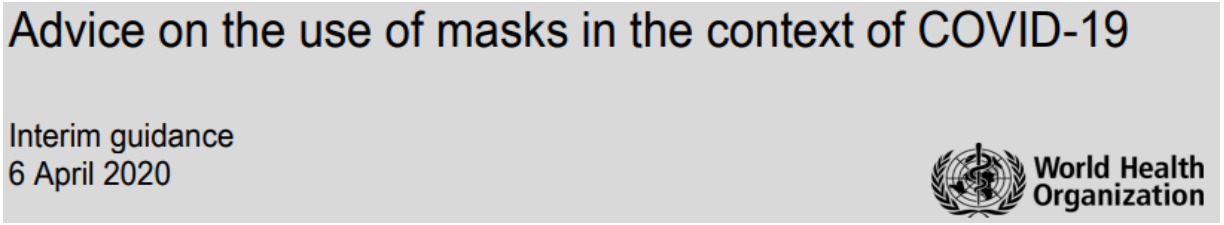
WHO guidance on PPE



https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125



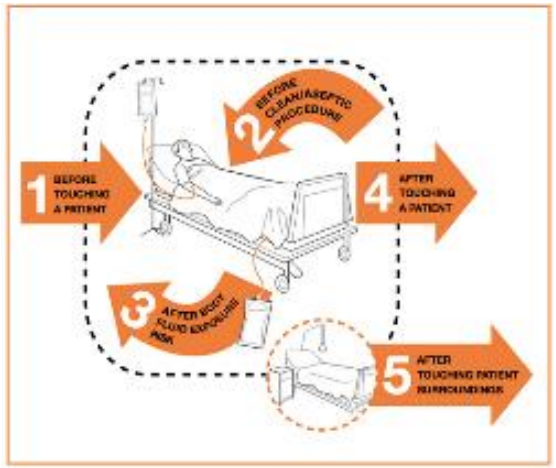
https://apps.who.int/iris/bitstream/handle/10665/331695/WHO-2019-nCov-IPC_PPE_use-2020.3-eng.pdf



https://www.who.int/publications-detail/advice-on-the-use-of-masks-the-community-during-home-care-and-in-health-care-settings-in-the-context-of-the-novel-coronavirus-(COVID-19)-outbreak

- What PPE to wear?
- By whom?
- When?
- How?

WHO training on IPC: https://openwho.org/channels/covid-19



Standard precautions: Hand hygiene

How to put on and remove personal protective equipment (PPE)

Infection Prevention and Control (IPC) for Novel Coronavirus (COVID-19))

OpenWHO Training - IPC Channel

- 9 courses and more coming!
- Translated in over 20 languages
- Over 1 million enrollments

https://openwho.org/channels/covid-19

World Health Organization

OpenWHO Training - IPC Courses

Infection Prevention and Control (IPC) for COVID-19 Virus

COVID-19: How to put on and remove personal protective equipment (PPE)

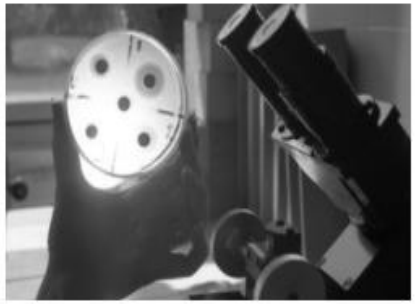
Standard precautions: Hand hygiene

Standard precautions: Waste management

Standard precautions: Environmental cleaning and disinfection

Standard precautions: Injection safety and needle-stick injury management

Infection Prevention and Control (IPC) core components and multimodal...



Basic microbiology

Risk Communications materials

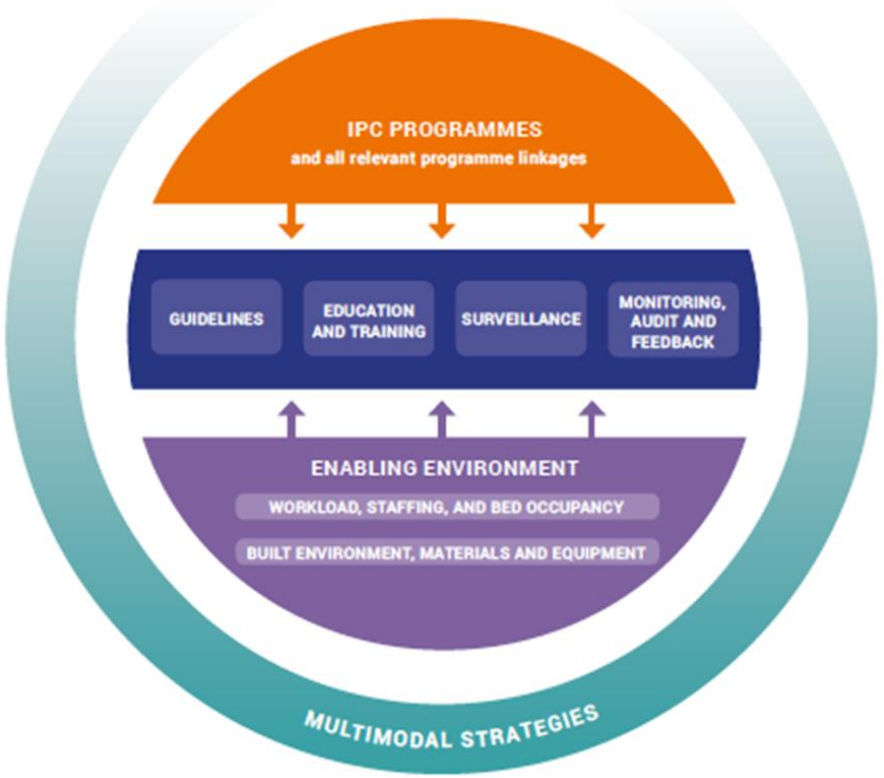
How to wear a fabric mask

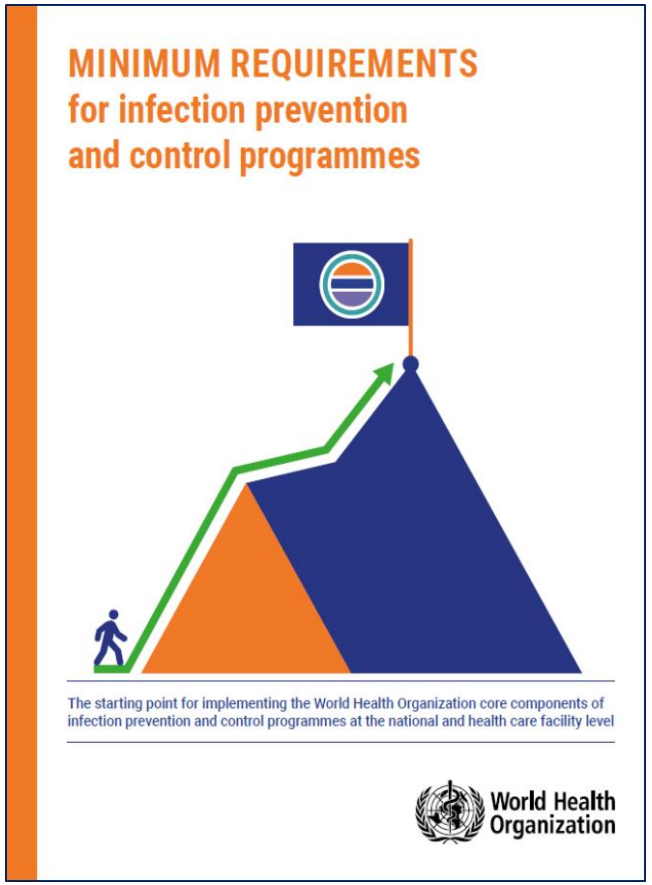
How to wear a medical mask

WHO's 3-layer Mask Video

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/when-and-how-to-use-masks

IPC core components and minimum requirements

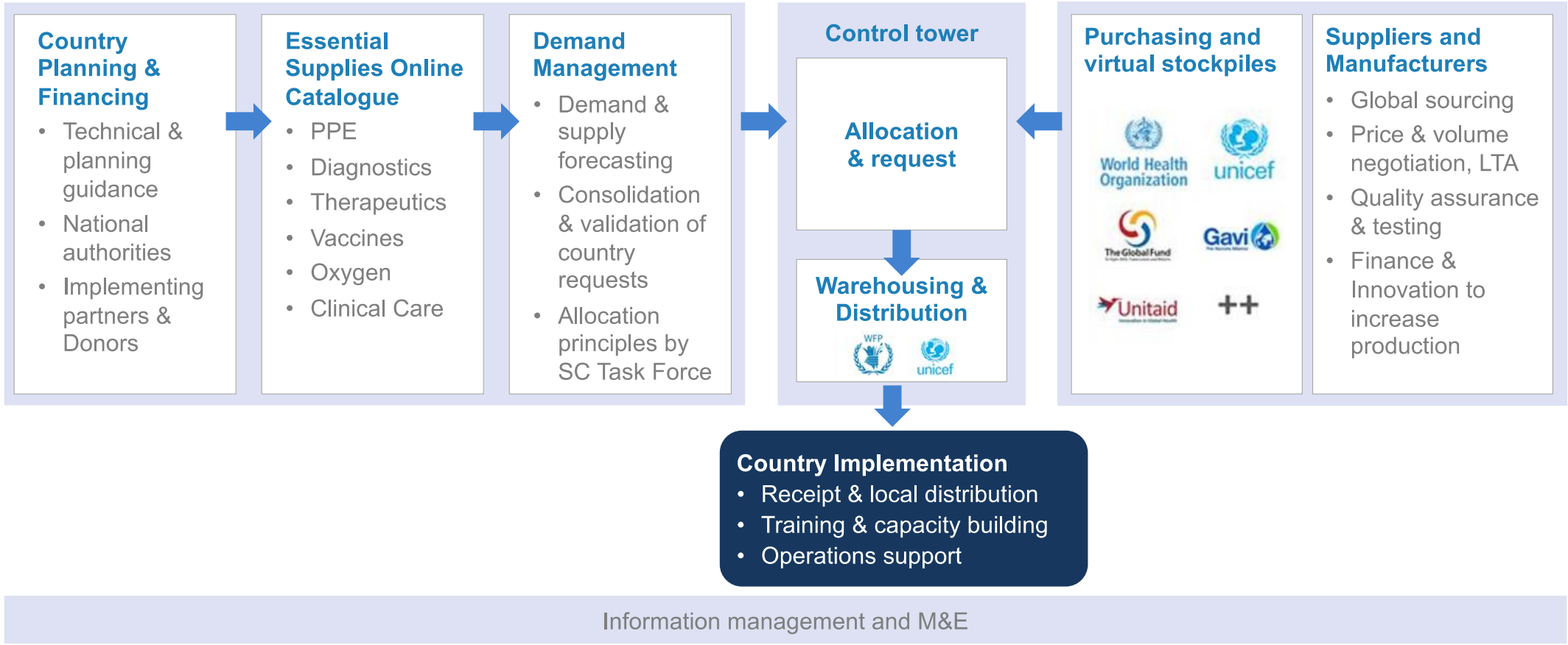




https://www.who.int/infection-prevention/publications/core-components/en/

https://www.who.int/infection-prevention/publications/core-components/en/

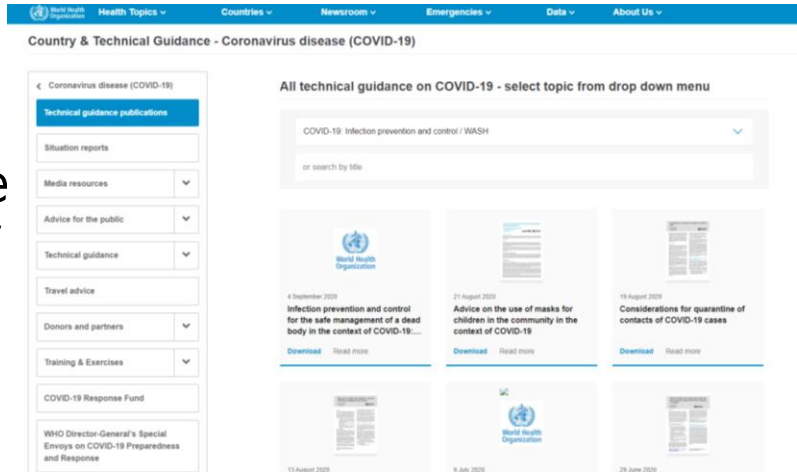
Coordinated demand, supply, allocation and distribution mechanism form the backbone of the COVID Supply Chain System



WHO IPC resources

- Surveillance protocol for SARS-CoV-2 infection among health workers Protocol
- Assessment of risk factors for coronavirus disease 2019 (COVID-19) in health workers: protocol for a case control study Protocol
- Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health care setting Protocol
- Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected
- Rational use of personal protective equipment for coronavirus disease (COVID-19)
- Health workers exposure risk assessment and management in the context of COVID-19 virus –tool, data collection and dictionary
- Cleaning and disinfection of environmental surfaces in the context of COVID-19 Considerations for quarantine of individuals in the context of containment for coronavirus disease (COVID-19)
- Advice on the Use of Masks
- Home care for patients with suspected novel coronavirus (nCoV) infection presenting with mild symptoms and management of contacts
- Q&A on infection prevention and control for health care workers caring for patients with suspected or confirmed 2019-nCoV
- Infection Prevention and Control for the safe management of a dead body in the context of COVID-19
- IPC guidance for long-term care facilities in the context of COVID-19
- Minimum Requirements for infection prevention and control (IPC) programmes

Existing and pending documents specific to HWs



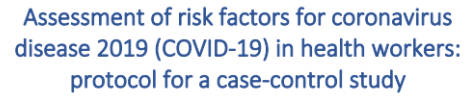
Existing:

- Considerations for public health and social measures in the workplace in the context of COVID-19 and *Annex to Considerations in adjusting public health and social measures in the context of COVID-19*
- Laboratory testing strategy recommendations for COVID-19: interim guidance
- Criteria for releasing COVID-19 patients from isolation *Scientific Brief*
- *IPC guidance documents including IPC during health care, Rational use of PPE etc.*

Pending:

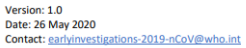
- Health workforce policy and management in the context of COVID-19 pandemic response. *Interim guidance in development*
- Occupational Health Rights and Responsibilities in the context of COVID-19. *Interim guidance in development*

Assessment of risk factors for coronavirus disease 2019 (COVID-19) in health workers: protocol for a case control study



Available on the WHO website of The Unity Studies: Early Investigations Protocols

https://www.who.int/publications/i/item/assessment-of-risk-factors-for-coronavirus-disease-2019-(covid-19)-in-health-workers-protocol-for-a-case-control-study



Other languages are available: French, Chinese, Arabic, Russian and Spanish

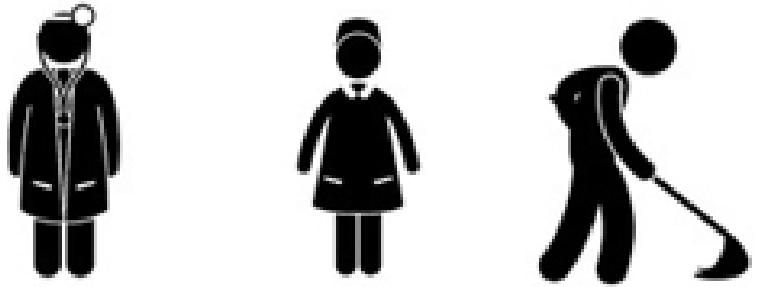
Objectives

Primary objective is:

- To characterize and assess the risk factors for SARS-CoV-2 infection in health workers with exposure to COVID-19 patients (primary objective).

Secondary objectives are:

- To evaluate the effectiveness of current COVID-19 IPC measures among health workers.
- To describe the range of clinical presentation for SARS-CoV-2 infection in health workers, including the duration and severity of the disease.
- To determine serologic responses in health care personnel with confirmed SARS-CoV-2 infection and in those attending patients but without COVID-19.

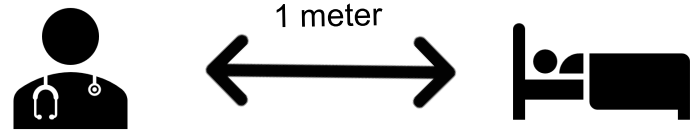


Study design

- Nested case-control study of health care personnel involved in care of confirmed COVID-19 cases
- Based on incidence density sampling for recruiting cases & controls
  - HW with confirmed SARS-CoV-2 infection will be recruited as cases
  - Other health workers in the same health care setting without infection will be recruited as controls (2 to 4 per case)
- Basic information and risk factor information will be collected from participants
- Paired serology samples from cases and controls for serology testing, one baseline serum during week 1 and another 3-4 weeks later

Definition of “Exposure to COVID-19 patients”

- A close contact (within 1 metre and for more than 15 minutes) with suspected/probable/confirmed COVID patient



OR

- Indirect contact with fomites (ex: clothes, linen, utensils, and furniture, etc), materials or devices or equipment linked to suspected/probable/confirmed COVID patient.

Case eligibility criteria (Health workers)

Inclusion criteria:

- Health workers in health care settings exposed to COVID-19 patients within 14 days of the confirmation test
- Being a confirmed case of COVID-19

Exclusion criteria

(only for the analysis – will include in descriptive analysis)

Health workers who have a confirmed COVID-19 case among his/her household/ close contacts within the previous 14 days, except the COVID-19 patients they were exposed to

Control eligibility criteria

Inclusion criteria:

- Health workers in health care settings exposed to COVID-19 patients in the same facility as the case within 14 days of being enrolled as control;
- not be classified as a suspected OR probable OR confirmed COVID-19 case

Exclusion criteria:

- Health care workers who have positive serology for SARS-CoV-2.

Form number	Purpose of form	Collecting from whom?	When should it be collected?
HEALTH WORKERS			
Form 1	**Initial** reporting form	For health workers whether they are case or control	As soon as possible after laboratory confirmation of a health worker in a health care facility (**Day 1**)
Form 2	**Follow-up/completion** reporting form	For health workers: final outcome	At least 21 days after completion of Form 1 (**Day > 21 to 28**) Updates should be sought regularly, if all the required information is not available at the time of completing this form
LABORATORY			
Form 1 & 2	**Laboratory form (part of initial and completion forms)**	For health workers whether they are case or control	First sample: As soon as possible after confirmation of a health worker in a health care facility and controls are selected Second sample: at least 21 days after completion of Form 1 Updates should be sought regularly, if all the required information is not available at the time of completing this form
HEATH CARE FACILITY			
Form 3	Health care facility infection prevention and control assessment	For health care facility administrator	Needs to be filled out once for every health care facility involved in the study

Sample size calculation

- Multiple risk factors for COVID-19 are considered in the study questionnaire at both individual and institutional levels
- Sample size depends on outputs and hypothesis

Expected exposure to risk factors amongst controls (%)	Detectable odds ratio*	Number of cases required	Number of controls required	Total number of participants required
10	2	245	490	735
10	3	85	168	252
10	4	48	96	144
20	2	151	302	453
20	3	56	112	168
20	4	34	68	102
30	2	124	248	372
30	3	49	98	147
30	4	31	62	93
40	2	117	234	351
40	3	48	96	144
40	4	31	62	93
50	2	120	240	360
50	3	51	102	153
50	4	34	68	102

Go.Data Data Collection Platform

- WHO developed data template form for the questionnaires (both for HW and for the facility
- The facility's dedicated personnel can enter data directly into the platform
- Anonymized data is shared with WHO from the multi-centre sites
- Training and technical support from WHO

Data platform contact: Mo Yin at (MoYin@tropmres.ac)

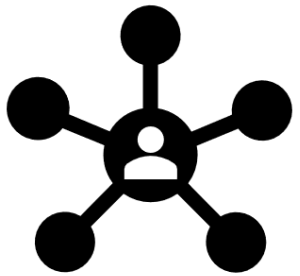
Possible outputs of the study

Objective	Parameter
To characterize and assess the **risk factors** for COVID-19 in health workers with exposure to COVID-19 patients	To characterise: • description of cases by potential risk factors (frequencies, proportion, etc). To assess: • adjusted OR and their 95% CI
To evaluate the **effectiveness of current IPC measures** among health workers.	Adjusted OR and their 95% CI of current IPC measures
To describe the range of **clinical presentation** for SARS-CoV-2 infection in health workers, including the duration and outcome of the disease	Frequencies, proportion of clinical symptoms, duration and outcome of the disease Proportion of asymptomatic and symptomatic fractions
To determine **serologic responses** in health workers with confirmed SARS-CoV-2 infection exposed to COVID-19 patients	• Antibody titre of both baseline and convalescent serum samples • Change in serum level of specific antibodies to COVID-19 virus (IgM, IgG, IgA) between baseline and convalescent serum samples, calculated using geometric mean titres (GMTs) (increase in titre) • Proportion of asymptomatic or pre-symptomatic/ subclinical infections (the proportion of individuals who reported no symptoms of COVID-19 infection of individuals seropositive for COVID-19)

WHO coordinated international multi-centre study

- This study started in May 2020 and last for 1 year
- Using this master protocol and its proposed tools.
- If a facility or institution is interested in participating, please email earlyinvestigations-2019-nCoV@who.int, with attention to Alessandro Cassini.

Please note that, to ensure data quality and completeness, participation in the international multi-centre study, health care facilities need to meet a number of criteria.



Criteria to consider for participation of research centres

Criteria	Details
Lead investigator at each site for the implementation and coordination	Have a member of staff who can dedicate time to the study implementation and data quality management.
Data management capacity	Capacity to perform follow-up of individuals.
Laboratory capacity for serology	• Capacity to perform appropriate blood collection procedure, specimen packaging, transport and storage. • Access to a laboratory with adequate infrastructure necessary to perform serological tests for SARS-CoV-2 infection (e.g. Enzyme-linked immunosorbent assay). • Informatics capacity: ability to use data collection tool; standardised patient records (EMR would be best); patient identifiers for linking

(see protocol section 2.2.3 for more information)

Steps to take

1. Review the protocol thoroughly
2. Determine if you are able to participate in the WHO international multi-centre
3. Ensure your centre meets criteria for the study
4. Ensure local national ethics approval
5. Sign WHO data sharing agreement
6. Familiarize yourself or whomever is doing the implementation with the Go.Data platform
7. Let us know if you would like to have a follow-up call

Acknowledgements

- Benedetta Allegranzi
- April Baller
- Madison Moon
- Alice Simniceanu
- Maria Van Kerkhove

Thank you for your attention

http://www.who.int/infection-prevention/en/
cassinia@who.int

Amnesty International report

- Health and essential workers have played an extraordinary role in the response to the pandemic
- They face enormous challenges in doing their jobs and at times have not adequately protected them
  - In some instances they've faced reprisals from the authorities and their employers for raising safety concerns
- Challenges:
  - Shortages of PPE
  - Inadequate pay and compensated in cases of occupational illness or death
  - Stigma

https://www.amnesty.org/download/Documents/POL4025722020ENGLISH.PDF (accessed 16 September 2020)

Call for action

- Ensure that employers provide adequate PPE to protect themselves
- Recognise COVID-19 as an occupational disease, and workers who contract COVID-19 as a result of work-related activities should be entitled to cash compensation and medical and other necessary care
- HWs concerns must be listened to and addressed in an appropriate manner
- Any attacks or acts of violence against HWs must be promptly investigated
- Reviews should be carried out regarding states' and other actors' preparedness for and responses to the pandemic
- Collect and publish data by occupation, including categories of health and other essential workers who have been infected by COVID-19

Next steps, after confirmation of enrollment

Once data sharing agreement and confidentiality forms have been signed with WHO and the confirmation of enrollment in ethical approval process has been made, you are ready to follow the next steps:

- Review and adapt the protocol to the local context (if needed)
- Estimation of expenses and serological kits needed
- Confirmation with WHO if we can provide the serological kits
- Estimation of funding budget request (for LMIC)