

Proposal

1. **Research Title:** (ภาษาอังกฤษ) Developing protocols for rationing scarce critical-care resources (intensive care unit (ICU) beds and ventilators) during the COVID-19 pandemic in Thailand

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3. **Introduction**

- Current situation of COVID-19

The emerging pandemic outbreak caused by a newly discovered coronavirus (COVID-19) is considered a significant threat to the global public health (1). The first cases of COVID-19 can be traced back to Wuhan, China, in December 2019 (2). COVID-19 then spread rapidly to other Chinese provinces as well as neighboring countries and has since reached all but a few corners of the world (3, 4). The number of confirmed cases surpassed 1 million cases on 2nd April 2020 (5). Patients with COVID-19 may be asymptomatic or exhibit mild to severe symptoms, with an estimated fatality rate of approximately 2%

among the medically attended patients (6). Currently, there are no specific drugs or vaccine available for treating this disease.

In Thailand, the number of confirmed COVID-19 cases is rising. As of 2nd April 2020, there have been 1,875 COVID-19 confirmed cases of which 23 severe cases are currently receiving intensive care treatment (5). For mild cases of COVID-19, initiating respiratory support is neither needed nor recommended. Once the disease progresses, pneumonia, severe pneumonia, acute respiratory distress syndrome (ARDS), and sepsis could be observed within the first few weeks of onset, requiring prompt respiratory support and intensive care to increase chance of recovery (7). The clinical management of patients with COVID-19 is considered to be similar to other viral infections such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), as well as sepsis and organ failure (8, 9). The initiating respiratory support is recommended to alleviate interstitial pneumonia characterized by severe hypoxia (10). Increasing number of hospitalized COVID-19 patients places a higher demand of clinical resources including intensive critical units (ICU) and mechanical ventilators.

Bangkok has experienced the highest number of COVID-19 cases in Thailand. A report by the Department of Medical Services showed that as of 8PM on 3rd April 2020, there were 109 Airborne Infection Isolation Rooms (AIIR)-ICU beds across 90 hospitals in Bangkok and surrounding areas. At the same time, 101 AIIR-ICU beds were occupied and 8 were vacant. Based on the forecasting model, as of 2nd April 2020, it is estimated that the demand for ICU beds in the capital will reach 190 beds by 19th April 2020 and by the end of April, it could reach over 300 beds, exceeding the supply of available AIIR-ICU beds in the greater Bangkok area. Whilst plans are in place for the creation of more AIIR-ICU beds, it is considered inadequate for the increasing demand (7). For ventilators' status, it is reported that 10,184 ventilators have been reserved throughout the country (7).

Current rationing process

Whilst the COVID-19 outbreak in Thailand remains a rapidly evolving situation, the current trajectory predicts a surge in patients requiring critical care (severe COVID-19 cases) which will result in a shortage of ICU beds and ventilators. The COVID-19 global pandemic has shown that even the most well-resourced health systems experience shortages of critical care resources in the height of the outbreak. In Lombardy, Italy, for instance, there were not enough ventilators to go around despite large efforts to increase supply (11). In preparation for the exceptional circumstances where demand for critical care resources will outstrip supply, there is an urgent need to establish explicit protocols to determine how resources are to be rationed and reallocated (12). This process, known as triage, will determine the

priority of access to critical care in the current pandemic (13). In these special circumstances where ICU beds and ventilators are scarce, the practice of rationing is unavoidable. The question therefore is not whether one should ration or not, rather how to ration in a fair and explicit manner or do so ‘in the heat of the moment’ (14).

There is a wealth of literature stating that bedside clinicians should not be tasked with deciding who gets access to live-saving care (12, 14, 15). Placing the responsibility of triage on the clinicians who are treating the patients can be morally distressing and mentally debilitating and is likely to result in varied criteria across hospitals which is ethically problematic (14). It is recommended that protocols on rationing be issued by the provincial/national level authorities and be uniformly applied across health facilities (14). This can make sure that rationing decisions are informed by wider societal values (e.g. protecting vulnerable populations, maximizing health benefit etc.) and capture resource-allocation trade-offs (11, 14). Furthermore, for an effective triage process, protocols need to be concise and easy-to-understand by health professionals, patients and their caregivers (16). Health professionals, technical experts (including ethicists) and the general public all need to be engaged in the development of the criteria and mechanism for rationing to ensure it reflects the priorities of society and to maintain public trust in the health system process. The protocols should not be developed in a ‘closed room’ manner (17). Given the current COVID-19 pandemic, this research is timely and will assist hospitals in implementing a fair and transparent approach to allocating scarce critical care resources that are high in-demand and are the last resource for saving lives of these severely affected patients.

4. Objectives

The main objective is to develop mechanisms for rationing both ICU beds and ventilators and establish criteria for allocation of these scarce resources that can be applied fairly and consistently across Thailand. These protocols (criteria and mechanisms) will be applicable at the point of demand exceeding supply in the exceptional circumstances brought about by the COVID-19 pandemic in Thailand.

The target audience for this work range from clinicians and Ministry of Public Health (MOPH) officials to patients, caregivers and the general public. The protocols will be developed in consultation with all relevant stakeholders to support the response efforts of the MOPH. The work will be disseminated to all stakeholders for wider use. The expected output is clear and concise protocols that are informed by a wealth of literature, guidelines, expert opinion and the values of the Thai society.

5. Research methods

A) Literature review

A literature review will be carried out using academic databases including PubMed and Science Direct, as well as ethical recommendations and existing international guidelines from countries such as Germany, Japan, South Korea, Switzerland, United Kingdom, United States of America. The project team will simultaneously review the critical-care triage policy (for ICU beds and ventilators) and guidance on resource allocation and bed flow management in Thailand.

B) Interviews with health professionals

HITAP will conduct qualitative interviews with the healthcare professionals who are working in ICU and non-ICU units in selected hospitals - Ramathibodi Hospital, Siriraj Hospital, Rajavithi Hospital, and Petcharavej Hospital. Given the current outbreak, the sample of interviewees will be kept minimal (e.g. 3-5 doctors and nurses) as the study should not disrupt current services. A semi-structured interview questionnaire will be developed which will adhere to the ethics standards in Thailand and will be pre-tested to ensure the instrument is valid and captures all the relevant aspects.

C) Develop the protocols and publish online

C1) Following activities (A) and (B), the protocol on the rationing ICU beds and ventilators in response to the COVID-19 outbreak will be developed by the research team under the supervision and guidance of the steering committee chaired by Dr.Viroj Tangcharoensathin. The first draft protocol will be consulted with stakeholders consisting of public health specialists, ethicists, psychologists, political scientists, medical lawyer, medical specialists, medical anthropologists and religious leaders.

C2) The second draft protocol will be developed following the consultation with the stakeholders. Once the second draft has been created, another stakeholders consultation will be arranged for the protocol finalization process. For protocol evaluation, the draft protocol will be published online for general public.

D) Present findings to Ministry of Public Health

The research team will convene a meeting with the MOPH to present a collective summary of the findings in response to the research objectives. The meeting will provide an opportunity to elicit expert input on the criteria and mechanism for critical-care resource allocation.

E) Final report

A final report will be prepared to describe the work that was undertaken and document the project findings. The report will contain the criteria and mechanism for allocation critical care resources (specifically ICU beds and ventilators) under exceptional conditions raised by the COVID-19 pandemic in Thailand and perhaps future outbreaks.

F) Manuscript in a peer-reviewed journal

A manuscript will be submitted and published in an open-access peer-reviewed journal on the critical care resource allocation protocols developed in response to the COVID-19 pandemic in Thailand. The manuscript will summarize lessons learned from this exercise and prospects for the future.

6. Benefits from this research

1. This study will support health care professionals, hospitals and policymakers for the allocation of critical-care scarce resources under a public health emergency.
2. This study will help relieve a moral burden upon attending physicians and ensure that the decision is fair, transparent, ethically appropriate and consistent throughout.

Inclusion criteria

- Participants agree and are willing to be interviewed.
- Participants sign an informed consent form.
- Participants are ICU and non-ICU doctors and nurses from public and private hospitals.

Exclusion criteria

- Participants withdraw consent from the interview.

7. Timeline

The estimated timeline for the tasks A-D is six weeks from project inception.

8. Ethical issues

There is minimal risk about personal information of interviewees. The research team will store data on a computer with an access code. The researchers will explain the details of the research project including its objectives, main approaches and expected benefits to the interviewees every time prior to signing the informed consent forms. The researchers are aware that the interviewees have the right to

accept or decline to participate in this research. In addition, in case the interviewees would like to withdraw their consent during the interview, the researchers will discontinue the interview immediately.

All personal information, sound records and interview transcripts of the interviewees will be kept confidential. The study results will be reported in form of overall narrative description, which cannot be tracked back to the individual informants.

12. ประวัติและประสบการณ์ของหัวหน้าโครงการ คณะผู้วิจัย และที่ปรึกษา

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