CRISIS DECISION-MAKING SUPPORT PATHWAYS

A CONCEPTUAL FRAMEWORK FOR MALAYSIAN HOSPITALS

Key Members: intensivists, emergency physician, adult physicians, infectious disease specialist, palliative specialists, ethicists.

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Content:

Separate document: Crisis Decision-Making Support Pathway Flowchart

A. Preamble

1. Providing medical care in a pandemic will always be faced with challenges as it deals with massive numbers of patients and the number who become critically ill is very unpredictable. This chapter has been included in this best practice document to provide some guidance for hospitals in the unfortunate event of a surge of critically ill patients beyond the ability of available resources and workforce. It specifically addresses decisions regarding delivering intensive care to any critically ill patient during the COVID-19 pandemic and admission to the ICUs. It serves as a potential framework that Malaysian hospitals could adapt into their ICU bed management systems and expand to nearby hospitals (including private hospitals) to coordinate resources and care at a state or regional level.

2. It must be emphasised that this is only a guide and outlines the ethical principles, and offers a conceptual framework for handling such crises when necessary. Care must still be based upon the unique circumstances of individual healthcare settings, and nothing in this guidance should be misconstrued as a blanket policy statement.

B. Justification of Crisis Protocols

1. **Crisis protocols** are activated when a crisis causes a significant change in the level of care that can be delivered. (1). As resource scarcity increases, the availability of "space, stuff, and staff " becomes limited, necessitating a transition of focus from individual patient-centred care to public health–based obligations to the community. (2).

2. The time and opportunities to deliberate on the goals of care through an informed and thoughtful process with the patient, family, and team may not be present. Ethically, it is acceptable to consider a different flow of decision-making, which is safe, transparent, and just. (3). Crisis protocols should only be activated when threshold of ICU bed occupancy has reached 70% or more suggesting an inevitable shortage of ICU beds and equipment (4).

3. **Triage** is a form consensus and workflow during crisis when resources (e.g. ICU beds) has been fully depleted and that utilitarian approach is needed to prioritise these resources for those who will benefit the most.

C. The Principal Values That Inform This Guidance

1. **Duty to care and plan:** Each institution should establish a plan for what to do in situations of resource scarcity to cover the allocation or access to critical medical interventions (such as oxygen, intensive care beds and/or ventilators). Such a plan should establish a clear overall aim (WHO Living Guidance 2021) (5). Healthcare professionals should equally care for COVID-19 patients when the needs arise. Patients without COVID-19 require the same access to care as COVID-19 patients. There should be equal attention to the management of both COVID-19 disease and also other co-morbids of the patient.

2. **Fairness and equitable:** Decisions should seek to balance medical utility and equity, and not disadvantage any one group disproportionately (WHO) (5). Care should be considered for all patients, regardless of age, disability, social background, or COVID-19 status (Royal College of Physicians) (6). First-come-first-serve principle is not suitable for acute resource scarcity (7,8), but may be used as a tie-breaker (4,10). Allocation principles should be applied consistently. Fair rationing criteria and fair processes must be transparently applied, communicated with each patient and family and documented at all times.

3. **Accountability:** Measures are needed to ensure that responsible decision-making is sustained throughout the crisis.

4. **Inclusivity:** Input should be obtained with stakeholders and their views in mind. (5,12)

5. **Transparency:** Rationing criteria and processes should be publicly known and defensible.

6. **Reasonableness:** Decisions should be based on evidence, principles and values that stakeholders can agree are relevant to health needs, and these decisions should be made by credible and accountable members of staff. (12)

7. **Responsiveness:** Flexibility in a pandemic is key. There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis, as well as mechanisms to address disputes and complaints. Any system put in place must be reviewed regularly for revisions based on the latest evidence, and also audited (11).

8. **Solidarity:** All levels of leadership, management, and practitioners from different sectors and department of the healthcare system should put aside personal differences and pre-existing territorial barriers and bureaucracy, to come as one to plan and manage the pandemic crisis e.g. coordination of ICU beds among the public and private hospitals.

D. Islamic Bioethics Guidelines and Fatwas

Below are the excerpts from "Chapter 12: Triaging Protocol For ICU Admissions/Beds/Ventilators During Resource Crisis", in Bioethics and COVID-19: Guidance for Clinicians, 12th May 2021 (3).

Several guidelines have supported a systematic and transparent triaging with clinical decision-making tools or triaging officers/committees, of which includes the prohibition of withdrawing life-saving support to benefit the next patient but not if brain death or futility. There are considerations to advanced directives, altruism, random allocation, and healthcare workers in the flowchart by The Research Center for Islamic Legislation and Ethics (CILE). Some of the excerpts of the Fatwas are noted here:

1. **The European Council for Fatwa and Research (ECFR)** issued a fatwa(number 30/18): "Muslim physicians should comply with the administrative and medical regulations adopted by the hospital in which they work. However, if the decision is assigned to them, then they must utilize medical, ethical and humane principles. Withdrawal of life-saving equipment in order to benefit a patient coming after is not permitted. If the physician has no choice but to choose between two patients, then the first patient should be chosen (unless their treatment is deemed futile) and the patient requiring emergency treatment (over the patient whose condition is not so critical) and the patient whose successful treatment is more likely (over the patient whose successful treatment is unlikely). This is in accordance with fiqhi principle "ghalabatal-ẓunūn" and medical assessment." (10) http://www.e-cfr.org/

2. **The Assembly of Muslim Jurists of America** issued a fatwa on 4th April 2020 (Fatwa #87747) parts of the texts: "Human beings have the same intrinsic value...it is not permissible to favor some individuals receiving scarce resources over others...What is to be considered in prioritizing some over others is the degree of need; so the one in greater need should be prioritized, and if they have the same need (i.e., requiring the intervention for survival), the one with a greater likelihood of recovery, based on evidence-based clinical decision tools, should be given precedence. If such likelihood is equal, then those with the longer life expectancy should be given precedence. This is all consistent with the principle of 'procuring the greater good by forsaking the lesser.'...When applicable, service should be provided on a first-come, first-served basis...except when it may lead to stampedes or violence, or give unfair advantage to those capable of arriving early at a healthcare facility...If all previous considerations do not give precedence to some over the others, resorting to lottery is a principle that is endorsed...It is permissible for some people to decline placement on the ventilator, if its benefit is questionable..."(13) http://www.amjaonline.org

3. **The Research Center for Islamic Legislation and Ethics (CILE)** produced a flowchart and stated that: "The state of hardship a pandemic causes does allow certain things that are normally forbidden. Clear pre- specified guidelines should be prepared as part of every disaster plan, publicly shared and instituted early to effectively manage limited

resources throughout the pandemic with transparency and uniformity. The suggested algorithm is based on Islamic bioethical principles and balances utility with equity. It is designed to save the greatest number of lives without disadvantaging the vulnerable. Withdrawal is decided upon the consensus of a non-clinical team and is reserved for cases of brain death or futility. Muslim physicians are advised to follow the policy of their institutions and regulating medical bodies. If religious conflict with withdrawing or withholding life support is perceived, conscious objection may be considered." (14) https://www.cilecenter.org/resources/articles-essays/islamic-ethical-perspectives-allocation-limited-critical-care-resources

E. Expectations In Clinical Decision-Making

1. Clinical assessment and decisions for intensive care, if made, should never be done unilaterally and should be based on a consensus of at least two specialists from different disciplines who are directly involved in the clinical management of the patient. **Managing specialists should use clinical judgement (**balancing the benefits, risks, and burdens of care) **and considering patients' goals and values to guide management decisions;** and not based on prediction models for prognosis (WHO) (5), social status, or the availability of beds. They should consult with the head of department when there is a disagreement from another discipline and consider resolution pathways.

2. Decisions must be made early (within a few hours) and communicated to the patient and family in an empathetic way. Team communications must be maintained. All decisions and conversations should be documented.

3. Hospitals should involve higher-level hospital committee deliberation, ideally with ethics and medicolegal input, for complicated cases, provided it does not result in any untoward delays in care. Hospitals could also consider physician, patient-family support teams to handle difficult communication situations and coordinate, e.g. psychosocial support for stakeholders.

4. **From MSIC 2021 Guide (15) on "Frailty Scale":** "Age should not preclude ICU admission unless associated with advanced comorbidities or frailty. Increasing frailty in the elderly is associated with a poorer outcome due to poor physiological reserves in these patients (16,17,18). Similarly, individuals with disabilities (e.g., learning, visual or mobility) should not be precluded from ICU admission unless also associated with advanced comorbidities."

F. Intensive Care Clinical Considerations

It's feasible to consider inclusion criteria for intensive care, followed by identifying those facing imminent death or with end-stage diseases and other clinical factors (see below). When there are a few patients with similar clinical and prognostic factors and resources have been exhausted, factors such as pregnancy, life-cycle, first-come-first-serve, and front liners could be ethically used as tie-breakers.

1. Inclusion criteria for intensive care:

Variable	Inclusion Criteria for ICU Admission
Requirement for invasive ventilatory support	• Refractory hypoxemia (Spo2 < 90% on nonrebreather mask Fio2 > 0.85) • Respiratory acidosis with pH<7.2 Clinical evidence of respiratory failure Inability to protect or maintain airway
Hypotension	• SBP<90 mm Hg for adults or relative hypotension with clinical evidence of shock for all ages (altered level of consciousness, decreased urine output, other end-organ failure) refractory to volume resuscitation requiring vasopressor/inotrope support that cannot be managed on the ward

Care of the Critically Ill and Injured During Pandemics and Disasters: CHEST Consensus Statement, 2014 (8)

2. From MSIC 2021 Guide (15) – clinical factors to consider include:

a. Likelihood of benefit

b. Prognosis (based on severity of illness, existing comorbidities, and physical and cognitive status)

c. Life expectancy due to underlying disease(s) (eg. Cardiac failure, cancer, chronic kidney disease, chronic lung disease etc)

d. Anticipated quality of life that does not match patient's values and expectations (loss of independence or high level of care post discharge)

e. Wishes of patient

- "The urgency of admission is further determined by the patient's clinical status (stable vs. unstable) and specific needs such as life supportive therapies e.g. urgent dialysis for metabolic acidosis. Priority status may change when clinical condition of the patient evolves and a clearer history of functional status or comorbidities is acquired."

3. **Tie-breakers:** If there were more than one patient with the similar prognosis and clinical parameters, ethically, the subsequent layer of tie-breakers could be used. These include pregnancy, life-cycle (age), first-come-first-serve, front liners. A consensus must be made within the institution on the acceptable second or third layer of tie-breakers and communicated to all teams.

4. **Patients who will not benefit from intensive care criteria**:

Imminent death (physiologic futility):

- Cardiac arrest without return to spontaneous circulation despite defibrillation and cardiopulmonary resuscitation
- Brain stem death
- Hypoxic encephalopathy or persistent vegetative state
- No improvement in respiratory or hemodynamic status, or underlying organ dysfunction.
- Disseminated malignancy
- Persistence or development of triple acute organ failure

- In addition, for patients with chronic/severe life-limiting conditions (e.g., severe dementia, end-stage organ failure, metastatic cancer, etc.), of which pre-morbid functional status and survival are already poor, intensive care may not be beneficial. It may not be in their best interest as outcomes may lead to more suffering and distress. Clinicians should be familiar with prognostication of patients with chronic illness and apply this to the individualised care and decision-making for each patient. (Refer to prognostication tools)

5. Other tools and ethical considerations

Any objective scoring should remain an adjunct tool to assist clinicians in assessing and prognosticating the short and long-term mortality risks and should not be used as the sole decisive factor.

Below are the excerpts from "Chapter 12: Triaging Protocol For ICU Admissions/Beds/Ventilators During Resource Crisis", in Bioethics and COVID-19: Guidance for Clinicians, 12th May 2021. (3)

- Robert Truog et al. article: "The Toughest Triage," meant for COVID-19, it was suggested that "rationing to be performed by a triage officer or a triage committee composed of people who have no clinical responsibilities for the care of the patient (19), in which triage proceeds in three steps:
  - Application of exclusion criteria, such as irreversible shock;
  - Assessment of mortality risk using the Sequential Organ Failure Assessment (SOFA) score, to determine priority for initiating ventilation; and
  - Repeat assessments over time.

a. **Assessing mortality risks through short term survival:** A patient's physiologic severity at the time of referral, laboratory investigations, age, and mortality prediction – in Sequential Organ Failure Assessment (SOFA) – may be applied to assign a priority score, equating to the capacity to benefit in short term survival (20, 21). Paediatric patients may be scored the Paediatric Logistic Organ Dysfunction Score Calculator (PELOD-2) (22). Caveat: clinical measures and laboratory results must be readily available.

b. **Assessing mortality risks through long term survival and life cycle.** A patient with severe comorbid conditions with death likely within 1 year is assigned a score of 3 points. Patients with younger age are given fewer points than persons with advanced elderly age (Biddison, 9).

TABLE 1] Proposed Strategy for Ventilator Allocation in Epidemics of Novel Respiratory Pathogens

Principle	Specification	Point System			
		1	2	3	4
Prognosis for short-term survival	Adults (SOFA) or pediatrics (PELOD-2)	SOFA score ≤ 8	SOFA score 9-11	SOFA score 12-14	SOFA score > 14
		PELOD-2 ≤ 12	PELOD-2 12-13	PELOD-2 14-16	PELOD-2 ≥ 17
Prognosis for long-term survival	Prognosis for long-term survival (assessment of comorbid conditions)	...	...	Severe comorbid conditions; death likely within 1 y	...
Secondary consideration					
Lifecycle considerations	Prioritize those who have had the lease chance to live through life's stages (age)	Age 0-49 y	Age 50-69 y	Age 70-84 y	Age ≥ 85 y

Examples of severe comorbid conditions with associated life expectancy < 1 year are listed. This list is meant as a guideline and is not exhaustive. Patients meeting the criteria of < 1 y predicted survival based on what of the listed or other similar conditions should be assigned a score of 3. NYHA = New York Heart Association.
1. NYHA class IV heart failure.
2. Advanced lung disease with FEV_1 < 25% predicted, total lung capacity < 60% predicted, or baseline P_{AO_2} < 55 mm Hg.
3. Primary pulmonary hypertension with NYHA class III or IV heart failure.
4. Chronic liver disease with Child-Pugh score > 7.
5. Severe trauma.
6. Advanced untreatable neuromuscular disease.
7. Metastatic malignant disease or high-grade primary brain tumors.

Biddison et al. CHEST 2019

G. When Intensive Care is Not in the Best Interest of the patient.

1. If intensive care is indicated, but resources (beds/equipment/space/workforce) are not available or ready, they could be put on a waiting list, but not more than 6 hours. This situation should be reported to and managed by the Bed Management Unit (BMU) to decide and reallocate resources (e.g., seeking internal or external resources or a transfer of care).

2. **Patient's goals and values:** For patients of which intensive care is not in their best interest or those who desire a limit to intensive care, their priorities and preferences should be acknowledged in the tailoring of care plans (WHO) (5). The management and care goals of this group of patients need to be discussed considerably between the specialists and the family to ensure that expectations are clarified and aligned (3). Palliative care intervention, which includes intensive symptom management and psychosocial support, should be accessible at each institution that provides care for persons with COVID-19 (WHO) (5). (Chapter 2 on "DNR and EOL – Decision, Communication, and Management," Chapter 3 on "Palliative Care," and Chapter 4 on "Compassionate Care").

3. **Quality of care:** Difficult decisions or bad news must be communicated to patient and family early, consistently, in an empathetic/respectful way by the specialists, with compassionate and palliative care steps to follow. Clear and consistent team communication must be maintained. All decisions and conversations should be documented. Mortality audits (non-COVID-19 and COVID-19 cases) should be done at the hospital level. Review and revision of crisis protocols regularly according to the latest evidence or statistics.

4. **Reassessment of Patients** The overall condition of the patient admitted to ICU should be reassessed after a time period (e.g. 72 hours) among the multidisciplinary teams.

    c. Worsening: Consider revision in the goals of care and provision of palliative care.

    d. Unchanged: Consider continuing intensive care. Reassess daily to determine the continued need for intensive care.

    e. Improving: Consider continuing intensive care. If extubated with no significant organ failure, transfer to general wards and reassess daily to determine subsequent treatment.

H. Support and Oversight Of Difficult Decision-Making

1. **Bed Management Unit, BMU** (or other names with similar function) could be set up at the hospital level for the logistic purpose of coordinating resources and care:

a. To manage and to communicate to all teams the availability of resources (beds, equipment, space, and workforce requirements).

b. To expand surge capacities in advance.

c. To facilitate the reallocation of resources (seek internal or external resources or transfer of care) when indicated.

d. To communicate with BMU of other hospitals to coordinate resources and care at a state or regional level.

- BMU could be manned by trained medical officers and nurses who rotate, overseen by at least two senior administrators, and available at all times.

2. **Crisis Advisory Board (CAB)** (or other names with similar functions) could be set up to oversee and review the clinical, ethical, legal, and social aspects of challenging cases, especially when there is a dispute, appeal, or complexity. E.g. managing specialists disagreed on the indication for ICU admission for a patient; the ED department who appealed as a patient was held too many hours in the ED without a decision from managing teams; family members who requested a third-party review of decisions. CAB should:

   a. Review *immediately* individual cases referred by stakeholders.

   b. Review cases that did not receive intensive care.

   c. Communicate with clinicians and administrators if any concerns.

- CAB could consist of 2-3 senior clinical consultants who rotates or a committee. Hospitals may want to engage clinical/medical ethicists and legal experts to be part of CAB.

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Crisis Decision-Making Support Pathways Flowchart

A Conceptual Framework for Malaysian Hospitals

Non-COVID-19 or suspected/confirmed COVID-19 patients who fulfils the
INCLUSION CRITERIA for Intensive Care
(i.e. requiring invasive ventilatory or circulatory support)

Death is imminent OR End-stage & critically ill

YES

Break bad news and discuss on the next goals of care (which includes life-sustaining treatment and resuscitation) according to patient's values and preference. *(Chapter 2 on DNR and EOL – Decision, Communication, & Management)*

Provide palliative care and intensive symptom management
(Chapter 3 on Palliative Care)

Provide compassionated care steps - psychosocial support, visitation, goodbyes
(Chapter 4 on Compassionate Care)

(can be supported by a patient-family support team)

NO

Assessment by at least **TWO SPECIALISTS** of different disciplines directly involved in care, considering:

1. Likelihood of benefit
2. Prognosis (based on severity of illness, existing comorbidities, physical & cognitive status)
3. Life expectancy due to underlying disease (e.g. advanced cancer on palliative chemotherapy, NYHA class 3 or 4 despite optimal treatment)
4. Anticipated quality of life that does not match patient's goals and values (loss of independence or high level of care post discharge)
5. Wishes of patients especially those at terminal stage of disease

Tie-breakers: pregnancy, lifecycle, frontliner, first-come-first serve

Will benefit from intensive Care

YES

Bed Management Unit (BMU) receives on-going resources census (beds/ space/ equipment/ workforce) and communicates to ED, ICU and primary teams.
Call: _____

Resource available

Resource unavailable

BMU reallocate resources by:
- Internal arrangements,
- External arrangement, or
- Transfer of care

Any dispute, appeal, or complexity of case

Crisis Advisory Board (CAB) reviews the clinical, ethical, legal, social aspects of difficult cases; decides and communicates with stakeholders.
Call: _____

YES

NO

Break bad news and discuss on the next goals of care (which includes life-sustaining treatment and resuscitation) according to patient's values and preference.

Provide palliative care and intensive symptom management.

Provide compassionate care steps -psychosocial support, visitation, goodbyes.

(can be coordinated by a **Patient-Family Support Team**)

NO

Patient receives intensive care

Provide intensive care

Improving
Unchanged

UCC

Reassess patients (MDT)

Worsening

Consider managing in general ward

Family Comms

Maintain early, consistent, & empathetic /respectful comms with family

Encourage video or message from patient to family before intubation or deterioration.

Team Comms

Ensure clear and consistent team comms between teams (specialists, medical officers, and ward managers.

Clinical Governance

Ensure good documentation, conduct M&M audits, review and revise processes.