Development of a structured process for fair allocation of critical care resources in the setting of insufficient capacity: a discussion paper

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ABSTRACT

Early in the COVID-19 pandemic there was widespread concern that healthcare systems would be overwhelmed, and specifically, that there would be insufficient critical care capacity in terms of beds, ventilators or staff to care for patients. In the UK, this was avoided by a threefold approach involving widespread, rapid expansion of critical care capacity, reduction of healthcare demand from non-COVID-19 sources by temporarily pausing much of normal healthcare delivery, and by governmental and societal responses that reduced demand through national lockdown. Despite high-level documents designed to help manage limited critical care capacity, none provided sufficient operational direction to enable use at the bedside in situations requiring triage. We present and describe the development of a structured process for fair allocation of critical care resources in the setting of insufficient capacity. The document combines a wide variety of factors known to impact on outcome from critical illness, integrated with broad-based clinical judgement to enable structured, explicit, transparent decision-making founded on robust ethical principles. It aims to improve communication and allocate resources fairly, while avoiding triage decisions based on a single disease, comorbidity, patient age or degree of frailty. It is designed to support and document decision-making. The document has not been needed to date, nor adopted as hospital policy. However, as the pandemic evolves, the resumption of necessary non-COVID-19 healthcare and economic activity mean capacity issues and the potential need for triage may yet return. The document is presented as a starting point for stakeholder feedback and discussion.

INTRODUCTION

In March and April 2020, there was great concern that COVID-19 would overwhelm healthcare services, including in the UK, 1 with the potential for insufficient critical care beds, 1 2 ventilators, 3 4 and trained staff 5 8 and even oxygen. 9 10 In response, there were discussions about the potential need for triage, or fair selection of patients, if demand for critical care exceeded capacity. 1 11 This would require making decisions about provision of healthcare resource based on public health need (‘the greater good’) rather than on the needs of individual patients. 2 12

The response to the impending catastrophe was threefold. Critical care capacity was increased in all hospitals, 3 4 NHS Nightingale Hospitals were created to provide critical care capacity on a warehouse scale 5 6 and non-COVID clinical activity in hospitals was stopped wherever possible. Governmental and societal responses reduced potential demand through national lockdown. 6 7 8 The overall effect has been that the increased critical care bed capacity was sufficient to manage the increased demand of the first pandemic wave, and triage or restrictions on critical care access have not so far been required.

Triage of critical care is not a new concept. 17 19 During the influenza pandemic of 2009, the Department of Health produced a plan for critical care triage, 19 although, as the pandemic was less severe than anticipated, this was not needed. The over-riding principle of this document was to provide level 3 critical care only to patients thought to have ‘a good chance of survival with a reasonable life expectancy’. This tool described staged triage using a list of strict inclusion and exclusion criteria and a measure of acute physiological derangement (Sequential Organ Failure Assessment score 20 as the primary objective determinant of admission and withdrawal of life-support measures, as also described by others. 21 22 It included no objective assessment of frailty or underlying physiological reserve and raised concerns about inaccurate triage and prediction of survival. 24

In contrast to the previous influenza pandemics, the COVID-19 pandemic has a disproportionate impact on older patients. 23 In older adults, frailty and reduced functional capacity, in addition to comorbidities and degree of organ failure, are considered to impact the chances of surviving critical illness and therefore should be included in triage decisions.

In April and May 2020, several high-level publications from central organisations, including the National Institute for Health and Care Excellence (NICE), described the overarching principles of critical care triage during the COVID-19 pandemic and the ethical principles behind it. 25 26 27 Some suggested using objective clinical measures, such as clinical frailty scores, to guide decision-making. 28 However, none were produced as an operational document that facilitated ‘front line’ decision-making in the event that critical care resources were overwhelmed.

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Clinical ethics
The Intensive Care Society recently published clinical guidance on critical care capacity challenges during the COVID-19 crisis. The objective clinical decision aid in this guidance was limited to only age, a measure of clinical frailty and assessment for the presence of nine severe comorbidities. We believe this would be unlikely to significantly assist clinical decisions in the event of a demand-supply imbalance on critical care.

Consequently, in March and April when the need for local triage decisions appeared likely, and with no useful central guidance forthcoming, we undertook to develop a local operational document for managing access to critical care services when resources were insufficient. This was to be used only in the specific setting of insufficient resources such that demand for critical care services exceeded both local capacity and all additional capacity deliverable through regional and national mutual aid.

Throughout the development of the document (box 1), our aim was to seek stakeholder involvement. For the avoidance of doubt, this document has not proved to be needed and as such is not a policy document of our Trust. Rather, it remains in development. Publishing this document forms part of the stakeholder consultation around its development for the circumstance in which it might be needed. The next section and supplementary documents present the operational document in full. In this section, references are cited

**Box 1 Development document: a structured process for fair allocation of critical care resources—for use only in the setting of insufficient capacity or resource.**

This document is explicitly and only for use in times of inadequate resource, during which we need to change approach, and need a strong ethical framework in order to make fair decisions.

When resources are sufficient, decisions are based solely on what is best for each individual patient.

When resources are insufficient, decisions need to include a broader view on what is ethically fair for the wider community (society). This means factors such as fairness to others are included in decision-making.

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This process will be activated only when current resources are insufficient to meet the current or immediately anticipated demand. This means intensive care unit (ICU) treatment may not be available to patients who would normally receive it. We suggest that this document should also be used by other hospitals in the same region (who may be referring to a central resource) in order to ensure a consistent approach.

This document is most likely to be used to determine whether patients will have their care escalated to ventilation in ICU. In the setting of scarce resource, the decision may involve choosing whether escalation is appropriate, choosing between appropriate patients when insufficient ventilators are available or choosing between stopping ventilation for one patient to facilitate starting ventilation for another. In all these settings, this should only occur when all efforts have been made to seek resource to meet the needs of all patients who will benefit from them.

In a resource-limited setting, starting any patient on a ventilator should be considered a ‘trial of ventilation’ and this should be communicated during discussions with patient and family. The British Medical Association (BMA) (BMA 2020) supports this approach stating “there may be a need to make admission to intensive care or commencement of advanced life-support conditional upon response to treatment, for example, drawing on the concept of a time-limited trial of therapy”. Others also advocate this approach (Pittsburgh University 2020).

The BMA (BMA 2020) states that “all decisions concerning resource allocation must be:

► reasonable in the circumstances
► based on the best available clinical data and opinion
► based on coherent ethical principles and reasoning
► agreed on in advance where practicable, while recognising that decisions may need to be rapidly revised in changing circumstances
► consistent between different professionals as far as possible
► communicated openly and transparently
► subject to modification and review as the situation develops”.

These principles underpin the writing and use of this document.

The BMA document states “relevant factors predicting survival include severity of acute illness, presence and severity of co-morbidity and, where clinically relevant, patient age” and these are the factors used in this document.

There is a reasonably widespread ethical view that withdrawal of treatment from one individual in order to provide it for another may be ethically justified in a resource-limited setting (BMA 2020; Emanuel 2020; Cohen 2020; Pittsburgh University 2020; RCP 2020). However, this is not a high consequence action (Cohen 2020; RCP 2020; Truog 2020) and the legal position in the UK is currently under review. Current advice is to seek an urgent legal opinion. This document will be updated when that determination is available.
Clinical ethics

Box 1  Continued

Where a decision is made to withhold or withdraw some forms of treatment from patients on the grounds of resource allocation, it is crucial that those patients still receive compassionate and dedicated medical care and attention, as far as possible in the circumstances (BMA 2020). The clinical decision to implement ‘do not resuscitate decisions’ in patients judged unlikely to benefit from admission to ICU (eg, for deterioration that falls short of cardiac arrest) falls outside the remit of this document. However, the BMA ethical position on this is included in online supplemental data 5.

Decisions should be documented properly including the basis of the decision made and the context of restricted resource.

Assessment process

Assessment is a five-step process (figure 1). The first step confirms that demand is currently or is imminently expected to exceed supply and there follows a four-step assessment.

Figure 1  Summary of triage processes.

- Confirm demand/capacity situation.
- Assessment 1: Health assessment—physiology and comorbidities.
- Assessment 2: Patient and family views.
- Assessment 3: Ethical factors.
- Assessment 4: Senior clinician opinion.

In summary, assess which treatment options are likely to provide meaningful benefit, discuss those options with patient and family/carers to obtain their views on the benefits and burdens of each option, discuss the ethics of the wider situation and combine this in an overall clinician judgement.

It is important to note that these decisions are of high consequence, stressful to make and often time-sensitive. Assessments need appropriate time and thought and should generally not be made at the bedside. Staff making the decisions may find the process highly stressful and access to Trust support through the Trauma Risk Management (TRiM) process is encouraged.

While there is no formal ‘triage team’, the full assessment requires three senior clinicians, at least one of whom is not directly involved in the patient’s care. Inclusion of multiple senior clinicians (NICE 2020a) and clinicians who are independent of patient care are judged by others to be good practice (Pittsburgh University 2020; Truog 2020).

Assessments 1 and 2 require a minimum of two senior medical staff (NICE 2020a).

Assessments 3 and 4 require a third senior medical staff member. One member must be a senior ICU clinician (RCP 2020; NICE 2020b).

There is an expectation that using this four-step assessment, clinicians will be able to come to a consensus decision.

Where there is disagreement between the three clinicians that cannot be resolved,

- In an emergency discuss with the on-call consultant respiratory or an additional ICU physician and another independent consultant clinician. A majority decision will suffice.
- If there is time, the clinical ethics committee can be asked to advise and aid the clinicians in reaching a decision.
Box 1  Continued

Where there is disagreement between the clinicians and the patient or family that cannot be resolved,
► An emergency legal opinion may be required.
► If there is time, the clinical ethics committee can be asked to advise.
Assessment 1, or assessments 1 and 2, may determine that escalation to ICU care is not appropriate at that time. If this is the case, the decision must be communicated and online supplemental data 1 thoroughly documented.

If assessments 1 and 2 conclude that in normal circumstances the patient would be referred for ICU care, or would continue ICU care, it is appropriate to then use assessments 3 and 4. Once complete, the decision must be communicated and online supplemental data 1 thoroughly documented.

Capacity: supply and demand
While the process of determining resource capacity is not part of this document, it is important to indicate the CURRENT supply–demand status at the point the decision was made. This classification system relates to specific treatments. For example, at a given point in time, some therapies (eg, non-invasive ventilation) may be available while others are more limited (eg, mechanical ventilation) (table 1). The pathway is only to be used when demand exceeds capacity (including exhaustion of mutual aid, ie, CRITCON 4).

Table 1 Resources available and demands on them

<table>
<thead>
<tr>
<th>Available (CRITCON 0/1)</th>
<th>Treatment currently available. Supply is greater than demand. Decisions about treatment will be based on patients’ wishes and best interests.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited (CRITCON 2/3)</td>
<td>Treatment currently available but in limited supply. Capacity may soon be exceeded if high demand. Decisions about treatment will be influenced by the need to prioritise.</td>
</tr>
<tr>
<td>Severely limited or at capacity (CRITCON 4)</td>
<td>Treatment at capacity. Demand exceeds supply of treatment. Prioritisation is essential. Treatment available only to those patients with highest capacity to benefit quickly.</td>
</tr>
</tbody>
</table>

It is also useful to consider, where appropriate information is available, the likely extent of anticipated demand on the system (eg, in the next 24 hours).
► Low or usual.
► High (up to double normal demand).
► Extreme (more than twice usual demand for the service).

Assessment 1: health assessment—physiology and comorbidities (what treatments are appropriate?)
Aim: This assessment considers multiple aspects of the patient’s current and long-term health to objectively determine the relative risk/chances of a patient surviving their acute illness and the extent to which they will make a successful recovery. Scores are used only to aid interpretation. The absolute scores are not used to determine a decision but rather to inform the decision-making process. Scores from different domains should not be summed.

The scoring system is based on a combination of factors which will impact on outcome:
► Acute physiological derangement/organ failure.
► Comorbid conditions.
► Physiological reserve/functional capacity.
► Age.

1. Acute physiological derangement /organ failure
Consider the Sequential Organ Failure Assessment (SOFA) score (table 2): increasing SOFA score is a measure of increasing organ dysfunction and is associated with higher mortality. Note that patients with COVID-19 pneumonia may have a disproportionately low SOFA score as the disease presents as a predominantly single organ disease but has a high mortality on ICU.

Table 2 Sequential organ failure assessment categories

<table>
<thead>
<tr>
<th>Specification</th>
<th>Point system (adapted from Biddison 2019)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prognosis for short-term survival (SOFA score)</td>
<td>SOFA score ≤8</td>
</tr>
</tbody>
</table>

Also consider the NEWS2 score (this is recorded in the patient’s Critical Care Assessment Form).

2. Co-morbid conditions
First consider any severe or life-limiting comorbidities (use online supplemental data 3 and 4).
Allocate a score for other comorbidities as outlined below. Note this is a non-validated scoring system and the scoring acts simply as a method of enumerating comorbidities.
Box 1  Continued

Major comorbidities (score 2 for each present)
- Congestive cardiac failure with symptoms on minimal exertion.
- Severe irreversible neurological impairment including dementia.
- Chronic pulmonary disease with symptoms on minimal exertion or pulmonary hypertension.
- Chronic liver disease with Child-Pugh score 7 or more.
- End-stage renal failure requiring dialysis.
- Clinically significant immunosuppression.

Less impactful comorbidities (score 1)
- Inflammatory bowel disease, rheumatoid arthritis and other collagen vascular disease requiring biological therapies
- Alcohol dependence
- Hypertension (apply only to patients with COVID-19 disease).
- Diabetes mellitus and end organ dysfunction.
- Clinical frailty score 4.

3. Functional capacity and physiological reserve
What is the patient’s functional capacity and degree of reserve, based on their abbreviated functional performance score (recorded in the patient’s Critical Care Assessment Form online supplemental data 2) and clinical frailty score (online supplemental data 3).

The clinical frailty scale is not applicable in those aged <65 years. In addition, extreme caution should be used in assessing clinical frailty and functional capacity in patients with learning disability, stable chronic disability, cerebral palsy, autism, neurodevelopmental or mental disability or health conditions. In these circumstances, a separate holistic assessment of risks, benefits and patient wishes should be made and multidisciplinary discussion, including families and carers where appropriate, may be particularly valuable.

4. Record age
While physiological reserve undoubtedly falls as age increases, chronological age is only one measure to be used in assessing the potential to benefit from escalation of treatment. The BMA states “A simple ‘cut-off’ policy with regard to age or disability would be unlawful as it would constitute direct discrimination.” Increased age is independently associated with lower survival after critical illness (Szakmany T 2019).

Assessment 2: patient and family views
If not completed already, an appropriate Treatment Escalation Plan (TEP) should be completed as part of assessment 2. The Mental Capacity Act must be complied with. If a patient lacks capacity, the clinicians must try to contact those close to the patient, where practicable and appropriate, in order to make a decision in the overall benefit of the patient (including contacting a legal welfare proxy if applicable) (NICE 2020a). If a second party has lasting power of attorney over medical matters, the clinicians must make efforts to consult that person directly. If this is not possible in an emergency, the clinicians must determine and act in the patient’s best interests.

Using the Critical Care Assessment Form, there should be an assessment of what the patient and family would choose regarding their care. This should include an assessment of their goals, the burdens of treatment they are willing to accept and what outcomes are acceptable after treatment.

Clinicians should be mindful of assessment 1 and other relevant information to assist the patient (and family and carers where appropriate) in understanding the likely outcomes from intensive care and whether they would recommend it, based on individualised likelihood of benefit.

Assessment 3: ethical factors
In addition to assessments 1 and 2, there is a need to consider broader ethical considerations. It is essential that these principles are considered as part of the decision-making process.

The ethical principles are described in greater detail in online supplemental data 5. Those using this document for the first time MUST read online supplemental data 5 before making assessment 3 and others should ensure they are familiar with the principles.
- Aim to save more lives and more years of life.
- We counsel against incorporating a clinician’s view on the patients’ future quality of life in decision-making—it is unlikely that clinicians can reliably judge this—but the patient’s view on quality of life is important.
- Age should not be used as a sole determinant of priority for admission to ICU.
- Patients with COVID-19 and other medical conditions should be treated equally.
- The duration of critical care treatment an individual is likely to require in order to recover may be a factor in allocating resources, as this impacts on availability of those resources for others.
- The framework should respond to changing scientific evidence.
- Removing a patient from a ventilator or an ICU bed to provide it to others in need may be ethically justifiable, but requires a legal opinion at this time.
- For patients with similar prognosis, who cannot be separated in other ways (eg, by all four parts of the assessment), a random allocation, such as a lottery, may be used. The four-stage assessment means this is likely to be rarely required.

Other ethical considerations are more complex and opinions differ considerably. Some judge that an individual’s potential to contribute to
Box 1 Continued

maintenance of the critical infrastructure throughout the epidemic may be considered in determining priority for allocation of ICU care. Others have proposed that people who participate in research to improve treatments or vaccines during an epidemic should be given some priority for treatment. If either of these factors is included, please read consideration 7 in online supplement data 5 and document fully.

Assessment 4
The senior clinicians—ST7 or consultant—including at least one who has seen the patient during this admission should then combine the information obtained above with their clinical experience and expertise, to form an opinion on the level of appropriate medical care for the patient or patients (whether that be escalation of current treatment, continuation of current ward-based treatment or withdrawal of life-sustaining treatment).

This practice is the bedrock of normal decisions about clinical care. For that reason, it is rational to include it in this process. Treatments should not be started if senior clinicians judge the patient will not be likely to survive or if they judge the likelihood of benefit too small.

This is consistent with NICE guidance 159 (NICE 2020) which states “take into account the impact of underlying pathologies, comorbidities and severity of acute illness on the likelihood of critical care treatment achieving the desired outcome” and “base decisions on admission of individual adults to critical care on the likelihood of their recovery, taking into account the likelihood that a person will recover from their critical care admission to an outcome that is acceptable to them” and “start critical care treatment with a clear plan of how the treatment will address the diagnosis and lead to agreed treatment goals (outcomes)” and “stop critical care treatment when it is no longer considered able to achieve the desired overall goals (outcomes)”.

References: see online supplement data 6.

by name and date in brackets to distinguish them from those in the introductory and discussion sections of this paper.

DISCUSSION
We re-emphasise this document is not in use and is not Trust policy. We are publishing it to promote discussion in wider society to inform us and others of the acceptability, value and content of such a document. It was developed because of a lack of national detailed operational guidance on the topic.

Most previous documents are either treatises on the ethics of the matter or policy documents that tend to emphasise universal access and fail to directly address actions when resources are inadequate. The document enables structured, explicit, transparent decision-making, in a situation we all hope will never arise. It is designed to improve communication and facilitate fair allocation of limited critical care resources.

The document was developed by a group of clinicians (from critical care, geriatrics, paediatrics, haematology and general medicine) and managerial and legal staff, whose experience includes Trust management and medicolegal practice. It combines clinical knowledge and experience, literature review, discussion and consensus. Although space does not allow the whole document to be produced, the appendices form an important operational component: readers are especially encouraged to read online supplement data 5 which expands on the ethical framework that underpins decision-making. The process of development was one of evolution and discussion and encouraged to read online supplement data 5 which expands discussion and consensus. Although space does not allow clinical knowledge and experience, literature review, and absence of care.29 Where critical care is not offered, other steps involving patient and clinician opinion were deemed central to this process. The process starts with—ideally is preceded by—discussion with the patient and family, or carers, about their goals, expectations and what they would wish to avoid. These conversations often come too late, and any process that can move them earlier in the patient health journey is to be supported. Assessments 1 and 2 provide clinicians and patients with information regarding likely benefits, possible burdens and outcomes for an individual patient and inform patient discussions. The process would not undermine or bypass advance directives or delegated power of attorney, and equally it is accepted that a patient cannot demand treatment that is unlikely to be beneficial. As emphasised by the Intensive Care Society, despite the limitations of a setting of inadequate resources, the process is not about deciding between care and absence of care. Where critical care is not offered, other appropriate care must be provided, whether this be ward-based medical care or palliative care to support the patient and family through the dying process.

Regarding assessment 3, the authors believe ethical and legal principles underpinning the document should be transparent.
and these are included in the assessment process and described in detail in the document’s online supplemental data 5.

During the document development, an early draft was shared with the local clinical ethics advisory group which includes patients, representatives of the local university, a hospital chaplain and clinicians from primary care, psychiatry and psychology. Detailed written feedback was provided which led to considerable discussion and revision. The areas of greatest discussion raised by the clinical ethics advisory group were around the application of clinical scoring of any sort, the legal issues arising from patients already established on a ventilator and ethical considerations of including non-clinical factors in resource allocation.

The legal aspect that generated most discussion was the possibility of removing a patient from a ventilator once established on it. Once established on a ventilator, a patient will usually lack capacity to make decisions for themselves because of sedation and the degree of illness. Decisions are then guided by the Mental Capacity Act (MCA) and must be made solely in the patient’s best interests. Any decision based on the principle of providing ‘the greater good’ would therefore be at odds with the MCA and would require a formal legal opinion.

The ethical aspect that generated most discussion surrounded the possible inclusion of ethical ‘tie-breakers’ in decision-making, that is, patient factors that might benefit wider society. The ethics advisory committee raised concerns that these might be used to give preferential treatment to healthcare workers (as some have advocated), that assessing an individual’s value to the pandemic response was too complex or even invidious and that inclusion of such aspects might erode public confidence in the decision-making process. After considerable discussion and acknowledging differences of opinion, these elements were retained but downgraded, accepting their complexity but acknowledging that in a complex situation, where all other matters may be equal, such complexity may need to be addressed directly. The ethics committee also suggested that deciding a patient’s resuscitation status was separate from the decision to admit to critical care, and thus beyond the remit of this document. After discussion, this was retained as the authors felt the two are clinically intimately linked and where a decision is made that critical care will not be provided, it is important to ensure that a discussion and decision is made regarding the role of resuscitation without critical care backup.

There are several limitations to this document. First, we have to date only sought opinions from a small group within one hospital and its clinical ethics advisory group to develop the operational document. The urgent need and the challenges and potential adverse impact of communicating complex issues more widely during the peak of a pandemic surge are explanations for this approach. Between the two groups who developed the document, there is considerable medical and non-medical healthcare, legal, ethical and lay experience and knowledge. Patient representation was achieved through the clinical ethics advisory group. It is explicitly because we seek broader opinion and discussion that we now chose to publish this document. Meetings and discussions were virtual rather than face-to-face and this may have impeded conversations and inclusivity. Use of virtual meetings was an unavoidable consequence of the pandemic and we actively sought to include all participants in discussions. It may have been useful to have a formal dissenting voice or counter view to broaden the discussion during development. In practice, many differing views were voiced and considered during the process including from the clinical ethics advisory group. Active inclusive discussion was undertaken to reach a group consensus. In terms of the content of the document, we have adopted a utilitarian approach and other options exist. Some may consider this unjust and prefer options such as ‘first come first served’ or similar. There is a significant challenge to embracing diverse ethical opinions when creating a ‘standard operational policy’, and for practical reasons, a final choice is necessary to make the document operational and useful.

This document, and any similar, may be deemed controversial, but the fact such a document has not been needed during the pandemic makes it an ideal time to prepare it. It is widely accepted that the extent to which different individuals will benefit from critical care admission will vary according to individual circumstances. When resources are insufficient to treat all patients, triage decisions, however unpalatable, must be made. If that decision is not to simply treat on a ‘first come, first served’ basis, some element of utilitarian planning is required to deliver fairness and to attempt to save the greatest number of lives. As the pandemic progresses, it is no longer acceptable to put non-COVID-19 healthcare ‘on hold’ and this may create capacity challenges and a need for triage that has not yet been encountered. We hope that discussing these issues in a setting when they are not imminently needed will provide space to think and discuss, so that we can receive feedback, and ensure any future document reflects not only the wishes of the individuals who have drawn it up—or the ethicists whose writings have informed it—but also the wider community that we serve, because these decisions are too important to be left to doctors.

In summary, we have developed a multi-assessment pathway to aid triage in the setting of inadequate critical care resource. The process avoids triage decisions being made on the basis of one diagnosis or comorbidity or a cut-off of a specific age or degree of frailty. It enables integration of a wide variety of factors known to impact on outcome from critical illness, combined with clinical interpretation and experience, to provide a broad-based assessment. It does not exclude any groups of patients, but aims to deliver a caring, considered and equitable individualised approach.

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