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Protocol

Onco Critical Care Society Consensus Criteria for the Admission, Triage, and Discharge of Critically Ill Patients with Cancer in the Intensive Care Unit: Protocol for a Modified Delphi Consensus Process

Developed Onco Critical Care Society guidelines committee

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Background and Justification:

The admission of a critically ill cancer patient to the Intensive Care Unit (ICU) is a complex decision at the intersection of evolving oncology therapeutics, critical care capabilities, and medical ethics.[1] While historical perceptions of poor outcomes for cancer patients in the ICU still persist, modern data demonstrate improved survival, particularly for those with reversible acute illnesses and responsive underlying malignancies.[2,3] However, this progress has led to new challenges: appropriate patient selection, equitable resource allocation, and the avoidance of non-beneficial or disproportionately burdensome care.

Currently, significant variability exists in ICU admission and discharge practices for oncology patients across institutions and regions.[4] This variability can potentially lead to both under-utilization of the ICU for patients with a high likelihood of benefit and over-utilization for those in the terminal phase of refractory disease.

There is a pressing need for a standardized, evidence- and consensus based framework to guide these critical decisions. Such a framework must move beyond the outdated dichotomy of "cancer vs. no cancer" and instead integrate key prognostic determinants: acute illness reversibility, performance status and frailty, tumour biology and treatment trajectory, and patient values and goals.[5,6]

<u>How admission/ discharge criteria are different from that of non-oncological patients:</u>

There are numbers of reason that render the admission / discharge criteria for this subgroup of patient different from non-oncological patients. In non-cancer patients, ICU admission decisions primarily rely on acute physiological derangement and reversibility potential. For cancer patients, a dual prognostic assessment is required. Severity of acute critical illness or organ failures can be assessed with usual severity assessment tool. At the same time, underlying cancer biology (histology, stage, molecular markers), treatment responsiveness, and performance status (ECOG/ Karnofsky) should also be assessed.[7,8] Studies demonstrate that while acute illness severity predicts short-term ICU

mortality, long-term survival is predominantly determined by cancer-specific factors such as disease status and response to therapy. For instance, a patient with relapsed refractory leukemia and septic shock has a different prognosis than one with newly diagnosed lymphoma with similar septic shock.

In general ICU practice, reversibility focuses on recovery of organ function. In oncology critical care, reversibility may also depend on administering cancer-directed therapy while providing organ support. A patient with acute respiratory failure due to pulmonary lymphoma infiltration may require mechanical ventilation while receiving chemotherapy. The "reversible" component is the cancer's is not only reversibility of organ dysfunction but also response to chemotherapy . This paradigm does not typically apply to non-cancer patients.

For many non-cancer patients with uncertain prognosis, ICU admission may be open-ended. For cancer patients with intermediate prognosis, a pre-defined time-limited trial (TLT) is often appropriate.[9,10]

Special cancer population need urgent ICU admission as they are potentially salvageable. For example, Hematopoietic stem cell transplant (HSCT) recipients, patients with CAR-T cell therapy and patients with haematological malignancy and neutropenic sepsis may be given priority for ICU admission.

In regard to triage and prioritisation, following are usually considered: whether curative vs. palliative cancer therapy, whether during induction chemotherapy vs. late-line therapy, whether first ICU admission vs. repeated admissions for progressive disease. Tumor lysis syndrome, superior vena cava syndrome with airway compromise, hyperleukocytosis with leukostasis, spinal cord compression with neurological deficits are some emergencies that are unique to cancer patients and demand specific triage pathways.

For non-cancer patients, discharge typically occurs upon physiological stabilization. For cancer patients, discharge planning must integrate oncology treatment schedules and other supportive care needs. For cancer patients with limited prognosis despite ICU care, discharge to palliative care is a distinct and important outcome. This requires early involvement of palliative care teams during ICU

stay, family and patient acceptance of transition in goals, seamless handover to palliative only care services. This pathway is more frequently utilized in oncology than other ICU populations.

Despite this uniqueness of this vulnerable group of patients, current guidelines do not provide the nuanced, disease-specific guidance required for oncologic critical care. Therefore, the present guidelines aims to fill this gap by providing clinicians, hospital administrators, and policymakers with clear, evidenced based and consensus-driven criteria to ensure that ICU resources are used justly and effectively for this vulnerable population.

Objective:

1. To develop a comprehensive guidelines providing explicit criteria and a procedural framework for the admission, triage, and discharge of adult critically ill cancer patients in the ICU.
2. To establish oncology-specific triage principles for use during periods of system strain
3. To define use of "Time-Limited Trials" (TLTs) of ICU therapy as a fundamental strategy for patients with prognostic uncertainty.
4. To provide clear criteria for safe and appropriate ICU discharge, including transition to ward-based care, palliative care units, or hospice.

Methodology

<u>Scope of the statement:</u>

This statement applies to patients with active hematologic malignancies or solid neoplasm who present with or develop a critical illness requiring consideration of ICU admission or admitted to ICU and being considered for discharge. It encompasses both emergency and planned admissions.

Delphi process

This study will be conducted under the aegis of the Onco Critical Care Society. The study protocol will be uploaded at www.oncoccs.com . No funding was received for the conduct or publication of this study.

A steering committee comprising 12 to 14 intensivists, oncologist, emergency physician with recognized expertise in treating oncological patients will oversee the project. An independent Delphi methodology expert, who is a member of the steering committee, will supervise the methodological conduct of the process to minimize cognitive and dominance biases. The Delphi expert will independently manage survey administration, anonymized data handling, and response synthesis. The steering committee members will not participate in voting during the Delphi rounds and will not have access to identifiable responses. The Delphi methodology expert will not participate in statement drafting or modification and will be the only individual with access to raw anonymized outputs for administrative purposes.

An international expert panel of 30-40 members will be constituted based on predefined eligibility criteria including demonstrated clinical expertise in oncology, critical care and emergency medicine, scholarly contributions (peer-reviewed publications, invited lectures), and leadership roles in the field. E-mail invitations will be sent to selected experts. Participation will be voluntary, and consent will be implied by completion of survey questionnaires. Experts will remain anonymous to one another until completion of the study.

All steering committee and panel members will declare potential conflicts of interest prior to participation. A separate Conflict of Interest (COI) supplementary document containing disclosures from all members will be provided.

The scope of the project will be defined through a structured review of relevant literature. Databases searched, timeframe, search strings, and key terminologies used to develop the first-round questionnaire will be provided in the Supplementary Material. Based on identified evidence gaps, the steering committee will draft initial clinical statements.

Survey questionnaires will be administered electronically (e.g., Google™ Forms or equivalent secure platform) and will include: Seven-point Likert scale statements (1 = strongly disagree; 4 = neutral; 7 = strongly agree), and Multiple-choice questions (MCQs) with predefined options.

A minimum of three Delphi rounds will be conducted. After each round, anonymized aggregate feedback including response distributions and summary statistics will be shared with participants. Statements not achieving consensus will be reviewed and modified by the steering committee within limits that preserve the original intent of the statement. If substantial modification alters the core meaning of a statement, this will be clearly highlighted in subsequent rounds and documented in the supplementary Delphi reports. Complete round-wise questionnaires, response distributions, and statement evolution will be provided as supplementary material. A Delphi process flowchart will depict participation rates, attrition, and outcomes across rounds.

Consensus, stability, and stopping rules

For Likert-scale items, agreement will be defined as scores of 5–7 and disagreement as scores of 1–3. Consensus will be considered achieved when ≥ 75% of experts vote for agreement or disagreement. Median and interquartile range (IQR) will be used to describe central tendency and dispersion. For MCQs, consensus will be defined as ≥ 80% selection of a single option.

Strong consensus (expert opinion unlikely to change with time) will be defined as:

≥ 90% agreement for any MCQ option; or Likert-scale items with a median of 6 or 7 (agreement) or 1 or 2 (disagreement), with ≥ 75% votes in the corresponding range.

Statements achieving consensus but not fulfilling criteria for strong consensus will be categorized as weak consensus (expert opinion that may evolve with time and should be interpreted on a case-by-case basis).

The predefined consensus thresholds are based on commonly accepted standards in Delphi methodology literature, including guidance from Nasa P and colleagues.[11]

Stability of responses will be assessed using the non-parametric chi-square (χ^2) test comparing response distributions between two consecutive rounds. A p value < 0.05 will indicate instability.

The predefined stopping rule requires demonstration of stability across two consecutive rounds, irrespective of whether consensus or divided opinion is observed, and when further modifications are not expected to produce meaningful change in responses. Statements with persistent divided but stable expert opinion will be reported as: "No recommendation can be made due to divided expert opinion."

Attrition bias will be assessed by comparing response distributions between rounds and, where feasible, between completers and non-completers. Round-wise response rates will be explicitly reported.

Statistical analysis

Statistical analyses will be performed using Microsoft Office 365 Excel (Microsoft Corp., Redmond, WA, USA) and IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA), as appropriate. Median, IQR, and percentage agreement will be reported for Likert-scale items, and percentage agreement for MCQs.

Data management and reporting

During the study, anonymized data will be securely stored by the independent Delphi methodology expert. Upon study completion, anonymized datasets will be retained securely by the first and

corresponding authors and made available upon reasonable request, subject to institutional administrative approval.

Clinical practice statements will be derived from statements achieving consensus and stability. Strong consensus statements will use directive language (e.g., “should”), whereas weak consensus statements will use conditional language (e.g., “may”). Identified knowledge gaps and research priorities will be explicitly reported.

The study methodology and results will be reported in accordance with the ACcurate COnsensus Reporting Document.[12]

Manuscript Writing and Review

The steering group will synthesize the evidence summaries and accepted recommendations into a cohesive draft guideline.

Planned Timeline

- Months 1 -2: Steering committee formation, finalization of scope and PICO questions.
- Months 3-5: Conduct systematic reviews and evidence synthesis for each domain.
- Months 5-6: Formation GDP.
- Month 5: First round of formal Delphi voting.
- Month 6 Analysis, revision, and second voting round .
- Month 7: Analysis, revision, and third voting round required
- Month 8: Drafting of full guidlines document.
- Month 9: Final revisions, formatting, and submission for publication.

Dissemination and Implementation Plan

1. Publication: Submission to a high-impact, peer-reviewed critical care or oncology journal .
2. Executive Summary: Creation of a one-page infographic and algorithm for clinical use.
3. Society Channels: Launch at the OCCS Annual Congress; publication on the OCCS website; dissemination through society newsletters and webinars.

Updating Plan

The GDP will recommend a formal review and update every five years, or sooner in response to major shifts in cancer therapeutics or critical care evidence.

References

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9. Quill TE, Holloway R. Time-limited trials near the end of life. *JAMA*. 2011;306(13):1483-1484.

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11. Nasa P, Jain R, Juneja D. Delphi methodology in healthcare research: How to decide its appropriateness. World J Methodol. 2021 Jul 20;11(4):116-129.

12. Gattrell WT, Logullo P, van Zuuren EJ, Price A, Hughes EL, Blazey P, Winchester CC, Tovey D, Goldman K, Hungin AP, Harrison N. ACCORD (ACcurate COnsensus

Reporting Document): A reporting guideline for consensus methods in biomedicine developed via a modified Delphi. PLoS Med. 2024;21:e1004326.

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Supplemental materials1

The guidelines will be categorized in several domains. Clinical questions for domains will be structured in the PICO (Population, Intervention, Comparator, Outcome) format. For each PICO question, a systematic literature search will be performed with the help of a librarian.

Databases: PubMed/MEDLINE, Embase, Cochrane Central Register of Controlled Trials.

Time Frame: From inception to the date of the search.

Search Strategy: A combination of MeSH terms and keywords related to Critically ill oncological patients will be used.