



MONASH
University



Australian Clinical Guideline for Physical Rehabilitation and Mobilisation in Adult Intensive Care Units

Administrative Report

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Organisation Responsible for Publication of this Guideline

Monash University,
Australian and New Zealand Intensive Care Research Centre (ANZIC-RC)

1 Scope of Guideline

This guideline provides a basis for clinicians to inform their clinical practice and for the development of hospital policies and protocols regarding the use of physical rehabilitation and/or mobilisation in adult ICUs. It is designed to support decisions related to when and how to use physical rehabilitation and/or mobilisation as a safe and effective treatment. This guideline provides an overview of the current evidence base described as a set of three clinical practice recommendations. This guideline is based upon:

- a systematic review of the literature to identify the highest quality and most recent evidence related to the benefit and/or harm of physical rehabilitation and/or mobilisation,
- assessment of the quality and certainty of evidence,
- consensus expert opinion in the case of lack of evidence or low certainty evidence,
- consideration of consumers' lived experience and views,
- considerations for implementation including practical information and resources for the adoption of the recommendations into clinical practice, and
- transparent documentation related to the decision making for each recommendation.

2 Funding

The guideline development was funded by the Australian Government NHMRC Centres of Research Excellence (CRE), a centre for research excellence, whose goal is to transform outcomes of critically ill patients in ICU (CRE-ICU, GNT2006514). All GDG members are independent from funders.

The CRE-ICU provided funding for MAGICapp licence, and salary support for management and administrative personnel.

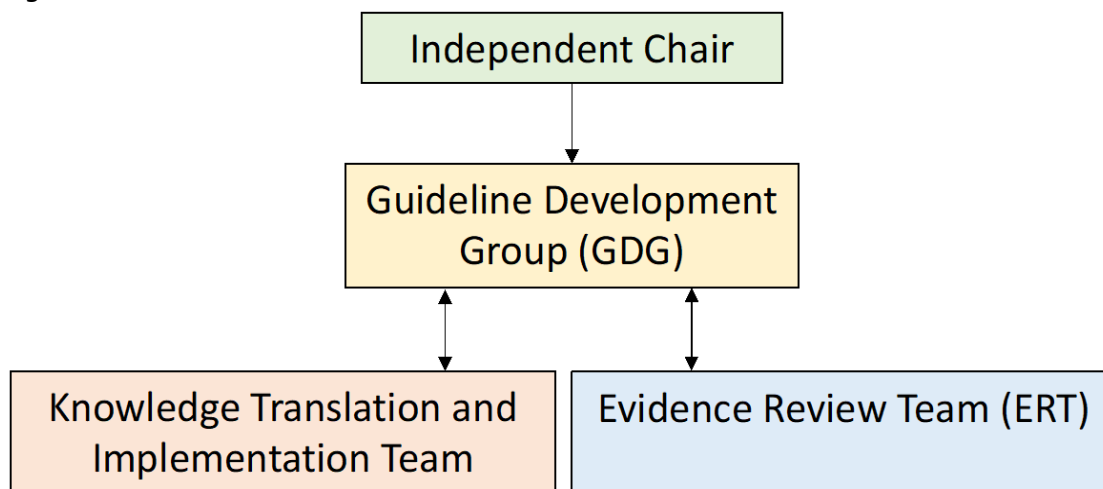
In addition, MAGIC Evidence Ecosystem Foundation provided a grant for the use of MAGICapp licence at a reduced rate.

Other than this, there was no additional funding for this guideline.

3 Governance

A governance structure was developed in the early stages of the project development, see Figure 1.

Figure 1. Governance Structure



3.1 Guideline Development Group (GDG)

Sally Green from Cochrane Australia agreed to act as the autonomous and methodological chair. For a complete list of GDG members and their areas of expertise, refer to Table 1.

The Independent Chair and the Clinical Chair assembled a multidisciplinary and diverse group of clinical and research professionals. To ensure a balanced mix of expertise and perspective, a targeted approach was employed for the selection of GDG members.

Individuals with lived experience and with expertise in physiotherapy, ICU, medicine, nursing, GRADE methods, health economics and knowledge translation were invited to the GDG. The resulting GDG comprised of physiotherapists, medical and nursing experts, clinical researchers, early career researchers, experts in knowledge translation, and consumers with lived experience of ICU admissions.

3.2 Membership

The role of the GDG involved contributing to the review of evidence and the development of content for guideline recommendations concerning the appropriate application of early mobilisation to aid in recovery from critical illness for patients admitted to an adult ICU.

3.3 Expectations

It was expected that members of the GDG would:

- Maintain confidentiality according to the Code of Conduct
- Understand the evidence supporting the guideline
- Participate in the scheduled introduction to GRADE methodology (a system for evaluating evidence and recommendations) or demonstrate prior experience and understanding of GRADE
- Adhere to agreed methods of communication, document generation and review
- Examine and provide feedback on documents between meetings as necessary
- Contribute to the drafting of recommendations
- Offer feedback on the draft guideline prior to publication

3.4 Roles and Responsibilities

All GDG members:

- Provided advice on the guideline scope including the topics and clinical question
- Reviewed and appraised original research related to specific clinical questions, utilizing the GRADE methodology as needed
- Evaluated the potential benefits and harms of physical rehabilitation and mobilisation
- Agreed upon the evidence to be incorporated
- Developed practical recommendations based on the review of evidence
- Assessed the acceptability and feasibility of recommendations
- Identified potential implementation challenges and suggested solutions to overcome them
- Ensured the guideline was worded appropriately for all end-users

3.5 Clinical and Methodology Chairperson

The independent chair of the GDG:

- Conducted meetings following the set agenda
- Facilitated group processes and ensured balanced participation of GDG members
- Maintained focus within the GDG to accomplish the desired meeting outcomes
- Described the evidence and evidence-to-decision process to assist GDG members in their decision making
- Coordinated the GDG and delegated tasks as required
- Worked with GDG to address any DOIs that emerged

3.5.1 Guideline Development Meetings

Each meeting featured a range of multidisciplinary expertise; however, it was considered essential for each meeting to have at a minimum of one representative with lived experience. A list of the invited experts is provided below. During each guideline development meeting, the GDG members voted on judgements for each of the aforementioned factors. Following review and discussion of the Evidence to Decision (EtD) framework, GDG were requested to vote on the direction of the recommendation (i.e., a recommendation for or against the intervention).

Table 1. GDG Members

Name	Discipline/Expertise	Organisational affiliation	Role
Independent Chair			
Sally Green	Co-Director Cochrane Australia	Cochrane Australia, Monash University	Independent Chair
Guideline Development Group			
Carol Hodgson	Clinician Researcher (Specialist ICU Physiotherapist)	The Alfred Hospital, Monash University	Clinical Chair
Shannah Anderson	Consumer		GDG Member
Sue Brennan	Melbourne GRADE Centre Director	Melbourne GRADE Centre	Methodologist and GDG Member
Tessa Broadley	Early Career Researcher/Project Manager	Monash University	Evidence Reviewer and GDG Member
Catherine Granger	Clinician Researcher (Fellow of the Australian College of Physiotherapists)	The University of Melbourne, The Royal Melbourne Hospital	GDG Member
Naomi Hammond	Clinician Researcher (Nursing)	The George Institute for Global Health	GDG Member
Lisa Higgins	Health Economist /Early Career Researcher	Monash University	GDG Member
Sherene Magana Cruz	Consumer		GDG Member
Jenna Lang	Early Career Researcher (Physiotherapy)	Western Health	GDG Member
Isabel Anne Leditschke	Clinician Researcher (Medical)	Mater Health	GDG Member
Neil Orford	Clinician Researcher (Medical)	Barwon Health	GDG Member
Selina Parry	Clinician Researcher (Fellow of the Australian College of Physiotherapists)	The University of Melbourne	GDG Member
Michelle Paton	Clinician Researcher (Physiotherapy)	Monash Health	Evidence Reviewer and GDG Member
Bronwyn Price	Physiotherapist/Early Career Researcher	Monash Health	GDG Member
Pam Taylor	Consumer		GDG Member
Andrew Udy	Clinician Researcher (Medical)	The Alfred Hospital	GDG Member

3.6 GDG

During the project development stage, the GDG included a network of physiotherapists, clinical researchers, experts in knowledge translation, and consumers with lived experience of ICU admissions. Table 2. outlines the GDG that agreed to sit on the committee and was convened on six occasions.

3.6.1 Meeting 1

The first GDG meeting. The group expressed the necessity for additional GDG members, as the majority were authors on the TEAM manuscript¹. The dominance of physiotherapy on the GDG and the importance of a consumer who could attend all meetings was also highlighted. It was determined that additional sites and alternative occupations would join the GDG, and an additional consumer would be found to join the GDG. Following this, the group discussed refining the guideline's scope, questions, and outcomes, particularly concerning the definitions of early, mobilisation, rehabilitation and critically ill, in addition to the possibility of multiple questions and recommendations. The group discussed the characteristics of ICU patients, including subgroups, which should be included or excluded from the guideline. Additionally, attendees discussed the guideline's intentions and scope, identifying two options: comparing groups to understand resource allocation; and focusing the guideline on the more severely ill ICU patients, where uncertainty exists.

3.6.2 Meeting 2

The second GDG meeting, aimed to continue the guideline PICO (Population, intervention, comparison, and outcomes) discussion. The meeting began with a discussion regarding patient inclusion criteria. It was determined that patients admitted to an adult ICU would be included, while studies where the entire population is in a long-term acute care facility (LTAC) or those in palliative care would be excluded. The group then discussed intervention details, determining that mobilisation and/or active physical rehabilitation that commenced in an ICU, where the intervention includes an active component targeting whole body rehabilitation, were suitable to include. It was decided that circumstances when the intervention was entirely electrical muscle stimulation (EMS)/ passive cycling / inspiratory muscle training (IMT) would be excluded. The group established the conditions of the comparator as being standard care or no active mobilisation and physical rehabilitation. Lastly, the group defined the outcomes and agreed to distribute a survey outlining the most critical outcomes.

3.6.3 Meeting 3

The third GDG meeting, resumed the discussion on the guideline PICO. The group discussed how comparisons between intervention and comparator would be made, regarding varying doses, timing and intensity of rehabilitation and mobilisation. An extensive discussion about the outcomes of interest followed, and the group decided to incorporate a hierarchy of outcomes, including mortality, health related quality of life (HRQoL), physical and cognitive function, complications of early mobilisation and economic outcomes. The group identified the next steps, and GDG members not involved in the TEAM trial voted to wait until the completion of the TEAM trial results for inclusion in the guideline, as it was noted to be the largest trial of physical rehabilitation and/or mobilisation to date, with a large number of Australian participants.

3.6.4 Meeting 4

The fourth GDG meeting took place, focusing on clarifying details about the included population. The consensus was to proceed with recommendations that can be made now, based on a mechanically ventilated population. The group agreed to retain the previously decided intervention, comparator, and outcomes, outlined in previous meetings. Following

this, the GDG discussed the EtD framework and established a timeline for submitting the guideline to the National Health and Medical Research Council (NHMRC).

3.6.5 Meeting 5

The fifth GDG meeting was held at two timepoints; due to the extensive discussion points. The population scope was determined as patients receiving invasive mechanical ventilation (IMV) only. The thresholds for determining an important difference were set as a standard mean difference (SMD) of 0.4, mortality of 2%, and adverse effects of 10%. The group thoroughly examined outcome measures, voted on the certainty of evidence for each outcome, initiated a discussion on the balance of benefits and harms and concluded that only conditional recommendations will be made in the guideline.

3.6.6 Meeting 6

The sixth GDG meeting commenced with an EtD discussion and vote, focusing on the overall benefits and harms related to outcomes, the certainty of the evidence, patient values, and preferences of each critical outcome, required resources, equity of the recommended intervention options, acceptability of early mobilisation from a stakeholder perspective, and the feasibility of implementing early mobilisation. Following this, the group deliberated on the wording of the guideline's recommendations and good practice statements.

Table 2. GDG Members and Attendance

Guideline Development Group							
Discipline/ Expertise	Representative	Attendance					
		Meeting 1	Meeting 2	Meeting 3	Meeting 4	Meeting 5	Meeting 6
Co-Director Cochrane Australia	Sally Green						
Clinician Researcher (Medical)	Isabel Anne Leditschke						
Clinician Researcher (Physiotherapy)	Catherine Granger						
Health Economist /Researcher	Lisa Higgins						
Clinician Researcher (Physiotherapy)	Carol Hodgson						
Consumer	Shannah Anderson						
Clinician Researcher (Physiotherapy)	Selina Parry						
Clinician Researcher (Medical)	Andrew Udy						
Early Career Researcher/Project Manager	Tessa Broadley						
Clinician Researcher (Physiotherapy)	Michelle Paton						
Melbourne GRADE Centre Director	Sue Brennan						
Physiotherapist/Early Career Researcher	Bronwyn Price						
Clinician Researcher (Medical)	Neil Orford						
Clinician Researcher (Nursing)	Naomi Hammond						
Consumer	Pam Taylor						
Clinician Researcher (Physiotherapy)	Jenna Lang						
Consumer	Sherene Magana Cruz						

■ = member in attendance

3.7 Methods for reaching consensus on recommendations

While developing recommendations for the guideline, members voted on recommendations and engaged in discussions to address any disagreements or discrepancies. In instances where consensus could not be reached, the Chairperson exercised the authority to make the final decision.

3.7.1 Methods for reaching consensus on good practice statements

Good practice statements were developed when there was high certainty that the desirable effects of an intervention outweighed its undesirable effects, but the body of supportive evidence was indirect. These good practice statements were developed based on a proposed structured process for the development of GPS's that includes applying GRADE guidance in a sequential order². These good practice statements satisfied the following criteria:

1. The message is necessary to actual health care practice
2. Implementation of the good practice statement would result in net positive consequences

Consensus on good practice statements was reached in the same way as recommendations; members voted on and engaged in discussions to address any disagreements or discrepancies. In instances where consensus could not be reached, the Chairperson exercised the authority to make the final decision.

3.8 Evidence Review Team

The evidence review team carried out systematic searches, evidence review and drafting of guideline test for the GDG to consider at meetings. The evidence review team and their responsibilities are outlined in Table 3.

Table 3. Evidence Review Team Members

Name	Affiliation	Role
Carol Hodgson	The Alfred Hospital, Monash University	Quantitative and qualitative analysis
Michelle Paton	Monash Health	Quantitative analysis
Tessa Broadley	Monash University	Qualitative analysis

4 Involvement of People with Lived Experience

Three consumers with personal experience of ICU admission, each having undergone physiotherapy as part of their critical illness recovery, actively participated in all stages of guideline development; in particular, decisions regarding the hierarchy of outcomes and EtD process. Shannah Anderson and Pam Taylor were engaged from the inception of the project and are both members of the GDG. After the first GDG meeting, Sherene Magana Cruz was invited to become a member of the GDG and contribute her lived experience and expertise. At each guideline development meeting, as least one attendee with lived experience was present. The consumer preferences and values within the EtD framework played a crucial role in incorporating the perspectives of those with lived experience.

4.1 Supporting consumers

People with lived experience were consulted and engaged early and consistently throughout the project. Including consumers in the development of the guideline was deemed crucial to foster patient-centred care, enhance guideline relevance and contribute to improved health outcomes and guideline quality. Moreover, supporting consumers in the guideline development process was important to strengthen transparency, accountability, and trust in the guideline, while facilitating effective communication and shared decision-making.

5 Particular risks, treatment and sociocultural considerations to Aboriginal and Torres Strait Islander peoples

The race or ethnic group of patients treated in intensive care with IMV varies among countries. In Australia, patients admitted to intensive care are predominantly white and of European descent. Although, Indigenous Australians are over-represented in the intensive care population and are admitted to intensive care at a younger age than non-Indigenous Australians. Approximately, 3.4% of patients admitted to ICU between 2017-2019 identified as Indigenous³. Treatment considerations in intensive care should acknowledge the physical, mental, spiritual, and cultural needs of the person admitted to intensive care.

6 Managing Declarations of Interest

The Chair and project team developed a policy and a Declaration of Interest (DOI) form in accordance with the NHMRC. The policy and DOI form were distributed to the GDG, and members were asked to declare and return any actual, perceived, or potential DOI to the Project Manager. The Chairperson and Project Manager reviewed the DOI and determined whether there were any conflicts within the GDG and devised an appropriate management plan. The DOIs of all GDG members were assessed according to the criteria presented in Table 4, and Declarations of Interest are outlined in Table 5.

6.1 Declaration of Interest Oversight

The Chairperson reviewed all DOI. During the meeting with the GDG on the 24 06 2021, they discussed assessment and adjudication of interests, considering the following key points from the NHMRC's Guidelines for Guidelines Handbook⁴:

- *Most individuals involved in guideline development have an inherent interest or stake in the process, often being the reason for their participation.*
- *The public may perceive personal interests of GDG members as potentially influencing decision-making, leading to concerns about objectivity and impartiality. Members might be considered to be overly attached to a field of research, a particular clinical practice intervention, an ideological viewpoint or an intellectual position—this might give the impression that they cannot make objective and unbiased decisions.*
- *Conflicts of Interest are predominantly financial in nature.*
- *A diverse mix of personal and intellectual interests is essential for fostering constructive and informed discussion and debate within the GDG.*

The Chairperson concluded that the majority of groups had no significant conflicts.

6.2 Updating Declarations of Interest

Prior to each recommendation meeting, GDG members were requested to declare any new or emerging interests, which were subsequently reviewed.

Table 4. DOI Assessment Matrix

		Interaction		
		High Risk Active financial relationship, including direct payment to individual of family member (e.g. consulting, advisory boards, paid speaker, investments or equity), payment in kind (e.g. air travel for conference other than as invited speaker), direct research support, non-academic publication (e.g. book deal) Direct intellectual interest (e.g. research study directly relevant to recommendation topic)	Moderate Risk Indirect intellectual interest, including unrelated or indirectly related academic activity or publication (e.g. research, journal article, textbook chapter) or advocacy. Indirect financial relationship (e.g. work resulting in payment to hospital or university department, including investigator on industry-sponsored trial).	Low Risk Dissolved or historical financial relationship (e.g. attendance at educational dinner meeting); remote financial relationship (e.g. unrelated payment or contract with hospital or university department); other minor interaction (e.g. visits from pharmaceutical representative). Personal experience
Entity	High Risk Pharma/biomedical industry, insurers	High	High	Low
	Moderate Risk Government, professional, consumer/advocacy bodies	Moderate	Moderate	Low
	Low Risk Academic or educational institutions/ publishers	Moderate	Low	Low

Table 5. Declarations of Interest

Declaration on Interests	
Name	Description of Interests
Sally Green	None to declare
Carol Hodgson	Financial Interests 1. <i>Meeting attendance/paid travel/receipt of meals</i> Speaking at international conferences (Heart Foundation, SMACC, ANZICS, CCCF, ATS, ISICEM, AAMVC, APA, ECMONet) on early mobilisation in ICU – support for travel or accommodation or meals (2016-2019, Maximum \$5000 (CCCF) per conference, no direct income).
	Intellectual Interests 1. <i>Indirectly related academic activity – employment/research</i> a. One grant as CIA comparing increased dose of early mobilisation to standard care in patients on prolonged IMV. Treatment of invasively ventilated adults with early activity and mobilisation (TEAM) Trial NHMRC funded (2017-2021, GNT2006514). b. One grant as CIA comparing early rehabilitation in patients on ECMO to standard care. ECMO-Rehab MRFF (2021-2023).
Shannah Anderson	Financial Interests 1. <i>Meeting attendance/paid travel/receipt of meals</i> Sits on other consumer groups and receives non-monetary compensation e.g., vouchers
Sue Brennan	None to declare
Tessa Broadley	Intellectual Interests

	<p><i>Indirectly related academic activity – research</i></p> <ol style="list-style-type: none"> 1. Authored publications that may be relevant to the work of the guideline committee <ol style="list-style-type: none"> a. TEAM randomised controlled trial (RCT) of early mobilisation in ventilated ICU patients (NEJM 2022). b. 2023 systematic review published in NEJM Evidence
Catherine Granger	<p><i>Financial Interests</i></p> <ol style="list-style-type: none"> 1. <i>Family member employment/financial interests</i> Funding sources of partner: 10th Rehab Conference for China; American Physical Therapy Association Combined Sections Meeting; ICU Rehab Symposia (Dubai); ASPEN Nutrition Science and Practice Conference; Asia Pacific Conference on Early Mobilisation and Rehabilitation in ICU; 13th International Conference of Rehabilitation Medicine (Taiwan); Australian Physiotherapy Association - Speaking at international and national conferences on early mobilisation and rehabilitation in ICU – support for travel or accommodation or meals (2016-2021, \$2000 per conference, no direct income). <p><i>Intellectual Interests</i></p> <ol style="list-style-type: none"> 1. <i>Indirectly related academic activity – employment/ research</i> <ol style="list-style-type: none"> a. Head of physiotherapy research at The Royal Melbourne Hospital where the department has an interest in mobilisation and rehabilitation. b. Teach in the Cardiorespiratory Physiotherapy teaching program at The University of Melbourne. <p><i>Additional Information</i></p> <ol style="list-style-type: none"> 1. <i>Partners’ intellectual interests (non-financial) - employment/teaching</i> Partner oversees the cardiorespiratory teaching program at The University of Melbourne. She developed an online subject for Masters of Rehabilitation Science in the Acute Setting – this subject is focused on assessment and rehabilitation of individuals within the ICU setting. She is the coordinator for this subject. She delivers all ICU rehabilitation related lectures and practicals within the Doctor of Physiotherapy program. 2. <i>Partners’ intellectual interests (non-financial) - employment/research</i> Partner is the first author on several publications that may be relevant to the work of the guideline committee since 2016: <ol style="list-style-type: none"> a. Parry et al (2018): Exploring the potential effectiveness of combining optimal nutrition with electrical stimulation to maintain muscle health in critical illness: A narrative review Nutrition in Clinical Practice 33 (6): 772-789

	<ul style="list-style-type: none"> b. Parry et al (2018): Implementing early physical rehabilitation and mobilisation in the ICU: institutional, clinician and patient considerations Intensive Care Medicine 44 (4): 470-473 c. Parry SM, et al (2017): What factors affect implementation of early rehabilitation into intensive care unit practice? A qualitative study with clinicians J of Crit Care 12 (38): 137-143 d. Parry SM, et al (2017): Factors influencing physical activity and rehabilitation in survivors of critical illness: A systematic review of quantitative and qualitative studies Intensive Care Medicine 43 (4):531-542
Naomi Hammond	<p><i>Intellectual Interests</i></p> <ul style="list-style-type: none"> 1. <i>Indirectly related academic activity – employment/ research</i> Site investigator (RNSH) for the TEAM Study which is an RCT of early mobilisation in critically ill patients.
Lisa Higgins	<p><i>Intellectual Interests</i></p> <ul style="list-style-type: none"> 1. <i>Indirectly related academic activity – employment/ research</i> <ul style="list-style-type: none"> a. One grant as a CI comparing increased dose of early mobilisation to standard care in patients on prolonged IMV. TEAM NHMRC funded (2017-2021). b. One grant as CIB comparing early rehabilitation in patients on ECMO to standard care. ECMO-Rehab MRFF (2021-2023). c. Authored several publications that may be relevant to the work of the guideline committee: Safety consensus of mobilising patients on mechanical ventilation (Crit care 2014); The ICU Mobility Scale (Heart and Lung 2014); Pilot RCT of early mobilisation in ICU (TEAM Pilot RCT CCM 2016); Pilot RCT of early mobilisation in ECMO in ICU (ECMO PT pilot ICM 2020); TEAM RCT of early mobilisation in ventilated ICU patients (NEJM 2022).
Sherene Magana Cruz	<p><i>Financial Interests</i></p> <ul style="list-style-type: none"> 1. <i>Meeting attendance/paid travel/receipt of meals</i> Sits on other consumer groups and receives non-monetary compensation e.g., vouchers
Jenna Lang	<p><i>Intellectual Interests</i></p> <ul style="list-style-type: none"> 1. Membership of Australia and New Zealand Intensive Care Society <p><i>Financial Interests</i></p> <ul style="list-style-type: none"> 1. I was a site investigator on the TEAM trial comparing standard (low-dose mobilisation) to higher dose early mobilisation.
Isabel Anne Leditschke	<p><i>Organisational Interests</i></p> <ul style="list-style-type: none"> 1. <i>Academic activity</i> <ul style="list-style-type: none"> a. Site Investigator for TEAM study.

	<ul style="list-style-type: none"> b. Local institutional projects involving intensive care rehabilitation and training. c. Invited speaker Advanced Diagnoses and Physiological Monitoring in Critical Care Symposium 2021 - "Delirium in Critical Care".
Neil Orford	<p><i>Intellectual Interests</i></p> <ol style="list-style-type: none"> 1. <i>Indirectly related academic activity – employment/research</i> AI on an ECMO Rehabilitation grant investigating the effect of early rehabilitation in patients receiving ECMO.
Selina Parry	<p><i>Financial Interests</i></p> <ol style="list-style-type: none"> 1. <i>Meeting attendance/paid travel/receipt of meals</i> 10th Rehab Conference for China; American Physical Therapy Association Combined Sections Meeting; ICU Rehab Symposia (Dubai); ASPEN Nutrition Science and Practice Conference; Asia Pacific Conference on Early Mobilisation and Rehabilitation in ICU; 13th International Conference of Rehabilitation Medicine (Taiwan); Australian Physiotherapy Association - Speaking at international and national conferences on early mobilisation and rehabilitation in ICU – support for travel or accommodation or meals (2016-2021, \$2000 per conference, no direct income). 2. CIA fellowship funding including AI and Val Rosenstraus Fellowship (2022-2026) 3. Sir Randal Heymanson Fellowship (2020-2021) <p><i>Intellectual Interests</i></p> <ol style="list-style-type: none"> 1. <i>Indirectly related academic activity – employment/ teaching</i> Oversee the cardiorespiratory teaching program at The University of Melbourne. Developed an online subject for Masters of Rehabilitation Science in the Acute Setting – this subject is focused on assessment and rehabilitation of individuals within the ICU setting. Coordinator for this subject and deliver all ICU rehabilitation related lectures and practicals within the Doctor of Physiotherapy program. 2. <i>Indirectly related academic activity – employment/ research</i> First author on several publications that may be relevant to the work of the guideline committee since 2016: <ol style="list-style-type: none"> a. Parry et al (2018): Exploring the potential effectiveness of combining optimal nutrition with electrical stimulation to maintain muscle health in critical illness: A narrative review <i>Nutrition in Clinical Practice</i> 33 (6): 772-789 b. Parry et al (2018): Implementing early physical rehabilitation and mobilisation in the ICU: institutional, clinician and patient considerations <i>Intensive Care Medicine</i> 44 (4): 470-473 c. Parry SM, et al (2017): What factors affect implementation of early rehabilitation into intensive

	<p>care unit practice? A qualitative study with clinicians J of Crit Care 12 (38): 137-143</p> <p>d. Parry SM, et al (2017): Factors influencing physical activity and rehabilitation in survivors of critical illness: A systematic review of quantitative and qualitative studies Intensive Care Medicine 43 (4):531-542</p> <p>Additional Information</p> <p>1. <i>Partners' intellectual interests (non-financial) - employment/teaching</i> Partner A/Prof Catherine Granger is head of physiotherapy research at The Royal Melbourne Hospital where the department has an interest in mobilisation and rehabilitation and teaches into the Cardiorespiratory Physiotherapy teaching program at The University of Melbourne.</p>
Michelle Paton	<p>Intellectual Interests</p> <p>1. <i>Indirectly related academic activity –research</i></p> <p>a. Completing PhD through Monash University on the effect of exercise dosage on outcomes from critical illness. Will be first author on some papers that will contain content relevant to this guideline.</p> <p>b. Site primary investigator of the TEAM trial and possibly other research in the area of mobilisation of critically ill patients.</p> <p>c. Membership of Australia and New Zealand Intensive Care Society</p> <p>2. <i>Directly related research</i> Led previous published systematic reviews on this topic and participated in trials included in the evidence</p>
Bronwyn Price	None to declare
Pam Taylor	None to declare
Andrew Udy	<p>Financial Interests</p> <p>1. <i>Research grants/contracts</i> Management Committee member for the INTENT and NUTRIENT studies - industry support studies of nutrition provision in the critically ill. (2018 – current, \$150,000).</p> <p>2. <i>Advisory board</i> Medical Advisory Board for the Oxyris, a continuous renal replacement technology (2018, \$2,000).</p> <p>3. <i>Unpaid consultancies and/or in-kind support</i> In-kind support (trial consumables) for the BONANZA RCT (CIA) (2018 – current, \$1.0M).</p> <p>4. <i>Meeting attendance/paid travel/receipt of meals</i> Integra Lifesciences - Travel/accommodation paid when presenting a sponsored lecture at the NSA meeting (2022, \$1500).</p>

7 AGREE II assessors independent of guideline development

Name	Expertise	Location	AGREE II score
Ilanthe Boden	Physiotherapist researcher	Launceston Hospital	5
Wendy Chaseling	Physiotherapist researcher	St George Hospital	7
Alex Poole	Nurse researcher	Royal Adelaide Hospital	7
Shane Patman	Physiotherapist researcher	University of Notre Dame	5
Benjamin Reddi	Intensivist researcher	Royal Adelaide Hospital	7
Peter Thomas	Physiotherapist researcher	Qld Health	6
Overall Score			6.2

8 Process for public consultation

The public consultation process was conducted in accordance with Section 14A of the *Commonwealth National Health and Medical Research Council Act 1992* and accompanying regulations. The public consultation period ran from 13 July 2023 until 18 August 2023.

A 'Notice of Public Consultation' was distributed to Australian Government Health Departments, advocacy groups and relevant professional organisations inviting comments and feedback about the draft guideline. The notice included a link to the draft guideline on the MAGICapp platform, a link to the feedback survey on Qualtrics, as well as links to the Technical Report and Dissemination Plan. A PDF copy of the draft guideline was also available.

The following organisations were approached to endorse the guideline during the public consultation period:

- ANZICS Clinical Trials Group
- College of Intensive Care Medicine
- Australian Physiotherapy Association
- Australian College of Critical Care Nurses

During the public consultation period, the 'Notice of Public Consultation' was the source of 83 unique page views. The guideline PDF was downloaded twenty-nine times via the notice and accessed via MAGICapp twenty-five times.

All feedback was reviewed by the GDG of the recommendations and all respondents were thanked for their input and provided with a response to their comments. Details of the feedback received can be viewed in the 'Public Consultation Submissions Summary'.

9 Public Consultation Submissions Summary

#	Section of Guideline issue	Respondent Comment	NHMRC Comment	GDG Response and Actions Taken
1.	Process for public consultation (administrative report)	The developer had indicated a de-identified version of the public consultation submissions summary will be made available when complete. This must include the details of submissions and the responses of the guideline development group to the submissions are provided as a separate document to NHMRC.	Please include a public consultation summary report when the final draft guideline is submitted to NHMRC.	The public consultation summary is included in section 9 of the administrative report.
2.	Guideline Development Group	A list of organisations that provide endorsement to the guidelines must appear in the final draft guidelines (after public consultation).	Please list organisations that will be invited to endorse the final guideline when it is completed.	The organisations who have endorsed the Guideline are listed in the Guideline Development Group section of Guideline. These include: <ul style="list-style-type: none"> • College of Intensive Care Medicine • Australian Physiotherapy Association • Australian College of Critical Care Nurses
3.	Systematic Review Evidence Table (technical report)	The evidence tables in the technical report (pages 12 to 19) should include an overview of the outcomes reported in each study identified/included.	Please add an overview of the outcomes for each study in systematic review evidence table.	The evidence table in the technical report has been amended to include an outcome overview column for each included study.
4.	References (Guideline, administrative and technical reports)	All supporting references for the recommendation should be listed. Ideally, all references should be clearly listed in the Guideline (within MAGICapp). Alternatively, the technical report should be referenced (within which the references can be found).	Please add supporting references for the recommendations in the Guideline. Alternatively, list the supporting references in the technical report and reference the report in the Guideline.	All the supporting references are listed in the Guideline, technical report and administrative report.
5.		The method used to arrive at the good practice statements should be clearly described in the administrative report.	Please add detail on the method(s) used to arrive at the good practice statement in the administrative report (e.g. voting or formal methods, such as Delphi).	Section “3.7.1 Methods for reaching consensus on good practice statements” is included in the administrative report. This section describes how the group developed the good practice statements by applying GRADE guidance in a sequential order.
6.	How to use this Guideline	The developers may wish to consider including the definition of ‘Good Practice Statement’ in the Guideline under ‘How to use this guideline’ on page 4-5. The definition is included on page 10 of the administrative report only.	Please consider adding a definition of ‘Good Practice Statement’ in the Guideline as suggested.	A definition of ‘Good Practice Statement’ has been added to the ‘How to use this Guideline’ section.

				“Good Practice Statements are ungraded statements that represent the GDG’s view of optimal practice. Good practice statements are developed when there is high certainty that the desirable effects of an intervention clearly outweigh its undesirable effects, but the body of supportive evidence is indirect and other criteria for their development are fulfilled.”
7.	Guideline, administrative and technical reports	To improve the user experience, it would be helpful for the in-text references were hyperlinked within the Technical Report.	Please consider, to improve user experience.	The in-text references have been hyperlinked in the Guideline, technical report and administrative report.
8.	Process for public consultation (administrative report)	It is suggested that the de-identified version of the public consultation submissions summary appear in the Administrative Report, or the developers may wish to provide as a separate document.	We note the placeholder for the de-identified public consultation submissions summary on page 17 of the Administrative Report.	The public consultation summary is included in section 9 of the administrative report.
9.	Dissemination and Implementation Plan	As part of the implementation plan, the developers may wish to provide suggestions for location adoption of the guideline.	Please consider this suggestion to improve guideline adoption at a local level.	A ‘local adoption’ section is included in the Dissemination and Implementation Plan of the Guideline.
10.	Dissemination and Implementation Plan	The developer could consider including measures for determining the extent to which key guideline recommendations are implemented	Please consider if resources allow.	An ‘evaluation strategy’ summary has been added to the Dissemination and Implementation Plan.
11.	Dissemination and Implementation Plan	The developer could consider including an evaluation strategy to assess the extent to which guideline recommendations are adopted into routine practice.	Please consider if resources allow.	An ‘evaluation strategy’ summary has been added to the Dissemination and Implementation Plan.
12.	Guideline and technical report	The evidence review was rigorous and appropriate. The review was performed using appropriate meta-analytic methods and the full spectrum of the evidence base seems to have been captured. The evidence synthesis and review were in line with the identified scope and clinical questions of the review.	No action required.	The Guideline Development Group thanks respondents for their comments.
13.	Executive Summary	The safety issues related to ER in ICU patients has always been key but recently has been impacted by important evidence from key RCTs including the TEAM study (which is appropriately reviewed in the guideline).	Please consider the wording suggested by the reviewer in the context of their interpretation of the TEAM study.	The Guideline Development Group has amended the wording of the good practise statements to address the respondents’ comments:

		<p>When meta-analysed, the existing breadth of the evidence does not show a clear signal for harm from the intervention; but the potential for harm related to the delivery of the intervention is clearly demonstrated in the TEAM study when its results are considered in isolation. In TEAM harm does seem to be related to the highest level of ER (intervention group) when compared to lower levels (control group). Benefit does seem to be identified for lower level ER over no ER at all from the general evidence base.</p> <p>So, in my opinion:</p> <ol style="list-style-type: none"> 1. This guideline recommends the implementation and delivery of ER compared to no ER but does not offer clear enough guidance on the risks of higher levels of ER in the guideline statements themselves (which will be read in isolation by many readers). 2. I would suggest consideration of somewhat more cautiously stated main recommendations with statements about the potential for harm with higher doses of ER. The group could consider these modifications: <ol style="list-style-type: none"> a. Good Practice Statement 8 ‘Discuss criteria for the safe implementation of physical rehabilitation and/or mobilisation for each patient receiving invasive mechanical ventilation with the multidisciplinary team, including respiratory and haemodynamic goals of care identifying that those receiving the highest level of ER may be more likely to suffer harm’. <p>Good Practice Statement 6 ‘Where possible, for patients receiving invasive mechanical ventilation in intensive care, discuss preferences for physical rehabilitation with the patient and/or surrogate decision maker including discussion about potential risks and benefits’.</p>		<p>“Good Practice Statement 8</p> <p>Discuss criteria for the safe implementation of physical rehabilitation and/or mobilisation for each patient receiving invasive mechanical ventilation with the multidisciplinary team, including respiratory and haemodynamic goals of care identifying that those receiving the most intensive level of physical rehabilitation and/or mobilisation may be at increased risk of adverse events.”</p> <p>“Good Practice Statement 6</p> <p>Where possible, for patients receiving invasive mechanical ventilation in intensive care, discuss preferences for physical rehabilitation with the patient and/or surrogate decision maker including discussion about potential risks and benefits.”</p>
14.	Evidence Review and Identifying Scope and Systematic Guideline Review	I note that the review includes a review of existing guidelines but only compares them to this guideline in broad strokes. There is a recognition of the varied rigour of those other guidelines and a recognition of the need for updated international guidelines.	No action required.	The Guideline Development Group thanks respondents for their comments.

	(technical report)			
15.	Executive Summary	My sole comment concerns Good Practice Statement 5. The studies from Corner et al. 2018 and Van Willigen et al. 2020 (both are referenced in this guideline) slightly contrasts with the recommendation to discuss early rehabilitation/mobilization goals with patients. Both of these qualitative studies concluded that patients had difficulty to engage in early goal setting due to their limited understanding of the recovery process or other priorities. Authors might therefore consider adding this limitation in the early stages of critical illness as well as the required support in goal setting from the interprofessional team. This might also apply to the chapter 'Values and preferences'.	Please consider adding a statement to reflect the limitations to patient involvement in the context of the studies referenced by the reviewer.	The Guideline Development Group has amended the wording of the good practise statement to address the respondents' comments: "Good Practice Statement 5 For patients receiving invasive mechanical ventilation in intensive care unit, goal setting for improving physical function with physical rehabilitation and/or mobilisation should be discussed with the multidisciplinary team and the patient or their family if possible. This should include both short- and long-term goals for physical rehabilitation and/or mobilisation noting that patients report difficulty in engaging in early goal setting due to their limited understanding of the recovery process."
16.	Evidence Review	A slight error on page 16 (2 nd line), GDG is written twice, and some references do not have a link.	Please fix error and consider adding a link to references.	The typological error has been fixed and additional references have been added.
17.	Evidence Review and technical report	Some useful evidence (not RCTs) may have been missed in the evidence review. However, given the scope and methodology, I believe the authors have been faithful to their objectives.	No action required.	The Guideline Development Group thanks respondents for their comments.
18.	Executive Summary	A major risk to interpreting this guideline in the real-world hinges on the definition of 'adverse event' or 'safety event'. This is true of many studies of physical rehabilitation in ICU. My opinion is that studies have been generally too conservative in labelling an incident as a 'safety event' (e.g. a transient drop in blood pressure which resolves with change of position or brief increase in vasopressor medication). My concern is that this guideline could steer clinical staff to being too fixated in avoiding any 'safety events', rather than working *with* the nursing and medical staff to optimise medication administration to enable / facilitate mobilisation.	The Guideline listed 'clinicians concern about patient safety' as one of the barriers to implementing rehabilitation and/or mobilisation. It is noted that the Guideline links to a 'safety criteria checklist' with consensus recommendations on what should be considered prior to mobilising adult mechanically ventilated ICU patient. Please consider if there are opportunities to further address the	The Guideline Development Group thanks the respondent for their comments. Further details regarding the safe implementation of this guideline have been added to the dissemination and implementation plan.

		The authors may like to consider defining safety / adverse events with this in mind, otherwise risk under-treatment through mobilisation.	'safety concern' barrier beyond the provision of the checklist.	
19.	Guideline	<p>I was impressed by the very rigorous and state of the art methods that were used. The process and the resulting guidelines are of highest quality and it is great to see that the GRADE methodology was used in such a rigorous way.</p> <p>I was involved in a HTA on this topic. We also found the literature to be very heterogeneous but the research question is also really challenging to address for at least two reasons: First, early mobilization is in place in many hospitals but performed in very different ways. "Early" ranges, depending on the hospital, from just 1 day to several days on the ICU and early mobilization may be performed for all patients (i.e. systematically early) or tailored individually (i.e. not just in terms of procedure but also timing). And of course, there are all the different ways how to perform the early mobilization.</p>	No action required.	The Guideline Development Group thanks respondents for their comments.
20.	Evidence Review	What I am missing a bit is a description of current practice in Australia (i.e. if, when and what type of early mobilization is done across hospitals) which is important to understand to then judge the applicability of the evidence. I am sure that this was discussed and reflected in the guideline development process (given the team that carried it out) but it is not so accessible as a reader.	Please consider if resources allow to assist international readers understand the current practice in Australia and apply the recommendations internationally.	<p>A description of the current practice in Australia has been added to the rationale section of the guideline.</p> <p>"In Australia, critically ill patients receiving mechanical ventilation are treated on a 1 to 1 ratio of patients to registered nursing staff and physiotherapists are available in most intensive care units. Therefore, physical rehabilitation is usually feasible with adequate staffing. The usual care arm of a recent RCT in Australia show a high level of mobilisation. There were 89% of patients in the usual care arm who achieved sitting over the edge of the bed and, 77% of patients able to stand prior to ICU discharge [12]."</p>
21.	Technical report	The other aspect I was missing is reference to the already existing systematic reviews on this topic. These reviews illustrate the challenges of summarising the evidence quite well. For example, this systematic review discusses these challenges (e.g. in terms of definition of early and systematic) in some more detail	Please consider acknowledging the evidence and research challenges in this area, if possible.	A new section 'Systematic Reviews on physical rehabilitation and mobilisation' has been added to 'Identifying Scope and Systematic Guideline Review' section of technical report to address the respondents' concerns:

		<p>https://ccforum.biomedcentral.com/articles/10.1186/s13054-020-03446-9</p> <p>I think it should be more highlighted how challenging the research is and that even the best clinical and trial groups (like https://www.nejm.org/doi/full/10.1056/NEJMoa2209083) will face substantial challenges. So the discussion may pick up these challenges a bit more in order to not do downplay the merits of the existing trials too much.</p>		<p>“There has been a number of comprehensive systematic reviews within the field of physical rehabilitation and mobilisation in adult ICU’s²⁻¹². The interpretations of this research are significantly challenged by the pronounced heterogeneity in study populations, variations in intervention strategies, and the lack of standardised definitions for ‘early mobilisation’. Patient populations vary in terms of diagnoses and lengths of stay, while intervention approaches differ widely in scope and intensity. Additionally, the unclear distinction between ‘early mobilisation’ and ‘standard care’ across studies adds complexity. This diversity in patient characteristics and interventions makes it challenging to draw clear conclusions from the research, complicating our understanding of the effects of early mobilisation in the ICU.”</p>
22.	Introduction	<p>Page 6, Defining physical rehabilitation and mobilization in the ICU: The authors should provide a reference for the statement, “Patients [...] can develop profound ICU-acquired weakness within 24-hours and develop impairments in their physical functioning [...] long after hospital discharge.”</p>	<p>Please consider referencing this statement</p>	<p>This statement has now been referenced; Hermans G, Van Mechelen H, Clerckx B, Vanhullebusch T, Mesotten D, Wilmer A, Casaer MP, Meersseman P, Debaveye Y, Van Cromphaut S, Wouters PJ, Gosselink R, Van den Berghe G : Acute outcomes and 1-year mortality of intensive care unit-acquired weakness. A cohort study and propensity-matched analysis.</p>
23.	Introduction	<p>Page 6 and 7, Objectives, Scope and Health question asked by this guideline: The main question the authors ask is very broad and when one examines closely, the evidence is primarily focused on the effectiveness of physical rehabilitation/mobilization on mortality, health related quality of life, physical function, cognitive function, and adverse events, etc. It would be helpful if the scope and outcomes were better explained earlier in the document. This information is presented much later on Page 16.</p>	<p>Please consider this suggestion</p>	<p>The executive summary, on page 9 of the guideline, now states “The key clinical question from the guideline - should physical rehabilitation and/or mobilisation be used as a therapy in adult critically ill patients in ICU? - was integrated with the key outcomes of interest. These outcomes included mortality, health related quality of life, physical function, cognitive function, and adverse events”</p>

24.	Executive Summary	Pages 9 and 10, Good practice statements: In Statement 7, who is consulting with the ICU physiotherapists, nursing staff and medical staff if these are the individuals who are doing the actual mobilization? Who should discuss the safety criteria in Statement 8 and what safety criteria should be used? What about safe mobilization techniques in Statement 11? Statement 9 should probably read “when an intubated patient is being mobilized out of bed”.	Please consider clarifying these statements (7 and 11) and rewording statement 9.	<p>The Guideline Development Group has amended the wording of the good practise statement to address the respondents’ comments:</p> <p>“Good Practice Statement 7:</p> <p>Physical rehabilitation and/or mobilisation in patients receiving invasive mechanical ventilation should include multidisciplinary engagement including ICU physiotherapists, registered nursing and medical staff.”</p> <p>“Good Practice Statement 9</p> <p>A medical officer with advanced airway skills should be available on site when an intubated patient is being mobilised away from the bed space.”</p> <p>“Good Practice Statement 11</p> <p>Provide education and training to key stakeholders on physical rehabilitation and/or mobilisation of patients receiving invasive mechanical ventilation in the ICU. This includes, but is not limited to, knowledge of precautions and contraindications, safe mobilisation techniques, strength assessment, functional training, use of specific equipment to facilitate safe physical rehabilitation and/or mobilisation and simulation training.”</p>
25.	Executive Summary	Page 10, Evidence to Decision, Harms and Benefits: This section summarizes the data presented in the Technical Report; however, neither the Guideline nor the Technical Report has references for the studies used to generate the forest plots. The data from these studies were summarized in Table 8 of the Technical Report and reproduced as the unnumbered Table in the guideline but again full references were not provided. More details should be provided in these tables relative to when treatment was initiated	Please consider the reviewer’s interpretation and whether more details are needed.	<p>The supporting references from the evidence table are now listed both in text and in the reference list.</p> <p>The Guideline development group thanks the reviewer for this comment, however, given the lack of reporting surrounding successful intervention delivery in both groups and, given intervention and control groups for</p>

		in the two groups and how often it was provided rather than reporting “started later” and “less frequent”.		these trials are commonly described relative to each other, further details could not be added to the table. This is addressed in the Future Research section of the guideline: “There were several important areas of future research that were identified. Future trials need to clearly define the control or comparator group, as it is unclear if differences in the results of trials of physical rehabilitation and/or mobilisation are due to the intervention or because the amount of rehabilitation and/or mobilisation in the comparator groups differ [32]. The timing of the intervention is considered important, where some small trials that have commenced very early report benefit [33] compared to other trials where the intervention started later that did not show benefit [12].”
26.	Executive Summary	Page 13, Rationale: The discussion in this section is highly relevant; however, reference to previous guidelines should be provided. As mentioned above, the Technical Report should contain more details on timing and dose of treatments as well as a better description of adverse events and the patient population (including comorbid conditions if available).	If you agree with the reviewer’s interpretation, please consider the addition of more detail as suggested.	[19][20][21][22][23][24][25][26] References added.
27.	Executive Summary	Good Practice Statement 1 In the following statement on p.10, “deliver” should be replaced with “receive” All patients admitted to the ICU should be assessed and screened daily for suitability to deliver physical rehabilitation and/or mobilisation. The initial screening should occur as early as possible after admission to ICU, within 24 hours if feasible.		The Guideline Development Group has amended the wording of the good practise statement to address the respondents’ comments: “Good Practice Statement 1 All patients admitted to the ICU should be assessed and screened daily for suitability to receive physical rehabilitation and/or mobilisation. The initial screening should occur as early as possible after admission to ICU, within 24 hours if feasible.”
28.	Executive Summary	Good Practice Statement 2 The word “including” should be removed in the following section on p.10		The Guideline Development Group has amended the wording of the good practise statement to address the respondents’ comments:

		Each hospital should have a dedicated physical rehabilitation /mobilisation program in ICU which includes clinical champions, stakeholders (e.g. management, executive), education, equipment (e.g. tilt tables) and appropriate governance arrangements. Governance arrangements should include including ongoing quality evaluation, regular review, budget allocation, risk management and clear reporting frameworks including reporting to hospital executive.		“Good Practice Statement 2 Each hospital should have a dedicated physical rehabilitation / mobilisation program in ICU which includes clinical champions, stakeholders (e.g. management, executive), education, equipment (e.g. tilt tables) and appropriate governance arrangements. Governance arrangements should include ongoing quality evaluation, regular review, budget allocation, risk management and clear reporting frameworks including reporting to hospital executive.”
29.	Administrative report	There is a spelling mistake on p.10 of the word ‘qualitative’ in the administrative report (p.10).		The typological error has been fixed

References

1. Team Study Investigators, Group ACT, Hodgson CL, et al. Early Active Mobilization during Mechanical Ventilation in the ICU. *N Engl J Med* 2022; **387**(19): 1747-58.
2. Dewidar O, Lotfi T, Langendam MW, et al. Good or best practice statements: proposal for the operationalisation and implementation of GRADE guidance. *BMJ Evid Based Med* 2023; **28**(3): 189-96.
3. Secombe PJ, Brown A, Bailey MJ, et al. Twelve-month mortality outcomes for Indigenous and non-Indigenous people admitted to intensive care units in Australia: a registry-based data linkage study. *Med J Aust* 2023; **218**(2): 77-83.
4. NHMRC. 2016 NHMRC Standards for Guidelines. 2016 (accessed June, 9, 2023 2023).