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ESTABLISHING AN OPERATIONAL DEFINITION OF SARCOPENIA IN AUSTRALIA AND NEW ZEALAND: DELPHI METHOD BASED CONSENSUS STATEMENT

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Abstract: *Background:* Globally there are several operational definitions for sarcopenia, complicating clinical and research applications. *Objective:* The objective of the Australian and New Zealand Society for Sarcopenia and Frailty Research (ANZSSFR) Task Force on Diagnostic Criteria for Sarcopenia was to reach consensus on the operational definition of sarcopenia for regional use by clinicians and researchers. *Method:* A four-Phase modified Delphi process was undertaken in which 24 individuals with expertise or a recognised interest in sarcopenia from different fields across Australia and New Zealand were invited to be Task Force members. An initial face-to-face meeting was held in Adelaide, South Australia, in November 2017, followed by two subsequent online Phases conducted by electronic surveys. A final Phase was used to approve the final statements. Responses were analysed using a pre-specified strategy. The level of agreement required for consensus was 80%. *Results:* In Phase 2, 94.1% of Task Force respondents voted in favour of adopting an existing operational definition of sarcopenia. In Phase 3, 94.4% of respondents voted in favour of adopting the European Working Group on Sarcopenia in Older People (EWGSOP) definition as the operational definition for sarcopenia in Australia and New Zealand. *Conclusion:* With consensus achieved, the ANZSSFR will adopt, promote and validate the EWGSOP operational definition of sarcopenia for use by clinicians and researchers in Australia and New Zealand.

Key words: Sarcopenia, definition, consensus, delphi.

Introduction

Sarcopenia is defined as an age-related disease of low muscle mass and low muscle strength or function (1). Sarcopenia is of increasing clinical importance due to growing evidence of its health implications and the increasing proportion of older people in the population. Sarcopenia has been associated with an increased risk and rate of falls (2), fractures (3), functional impairment (2), metabolic syndrome (4), hospital admission and readmission (2, 5) poorer prognosis in cancer (6) and liver cirrhosis (7), surgical morbidity (8) and all-cause mortality (2, 6). The clinical significance of sarcopenia as a distinct disease entity was established with the assignment of an International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code (M62.84) in September 2016 (9).

A 2017 systematic review and meta-analysis including 35 studies with 58,404 individuals estimated that the prevalence of sarcopenia globally was 10% in both men and women, and higher among non-Asian than Asian individuals (10). Others

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have reported the prevalence of sarcopenia to range from 1-29% in community-dwelling populations, 14-33% in long-term care populations and 10% in acute hospital settings (11). This marked heterogeneity is largely due to the different definitions applied to diagnose sarcopenia (12). Nevertheless, as the global population ages, the number of sarcopenic older adults is projected to increase substantially over the coming decades. As such, research is needed to help alleviate the burden of sarcopenia. For this to be effective, a clear consensus of what defines sarcopenia needs to be established.

Several operational definitions of sarcopenia have been developed (1, 13, 17) since the term was first coined almost 30 years ago (18). The most widely used operational definitions, combining both low muscle mass and function, are described in Appendix 1. While there is widespread agreement on sarcopenia as a disease entity, there is no uniform consensus regarding the operational definition of sarcopenia. This leads to challenges in comparing results from research studies utilising different definitions of sarcopenia, and undoubtedly is a source of confusion for both researchers and clinicians. Indeed, only one in five health care professionals know how to diagnose sarcopenia using the operational definitions available (19).

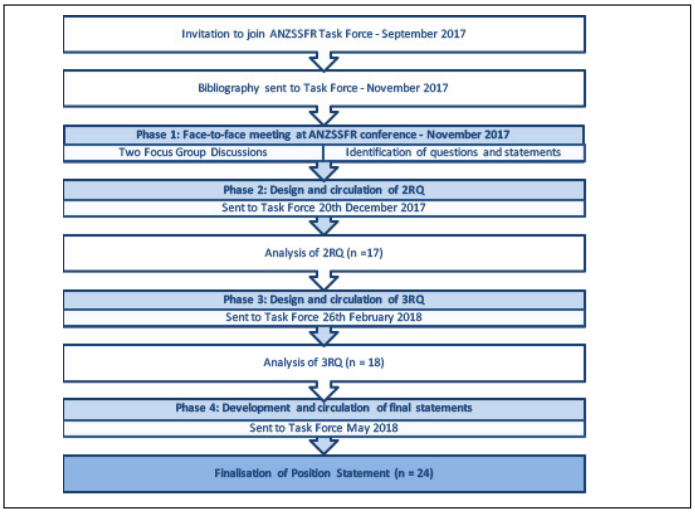
The most widely utilised consensus definition of sarcopenia in the research literature was developed by the European Working Group on Sarcopenia in Older People (EWGSOP) in 2010 (1). The EWGSOP definition includes an algorithm comprising gait speed, handgrip strength and muscle mass with cut-points dependent upon the individual's demographics (sex and height) (1). In 2014, this definition was modified and validated by the Asian Working Group on Sarcopenia in recognition of the impact ethnic differences have on cut-points for muscle mass, strength and performance (17).

The establishment of a demographically-appropriate operational definition of sarcopenia is required to unify researchers and provide clear guidance to clinicians for the diagnosis and treatment of sarcopenia (20). A group of individuals with an interest or expertise in sarcopenia were invited to join a Task Force and participate in a consensus-building collaboration with the aim of establishing an operational definition of sarcopenia for use by researchers and clinicians in Australia and New Zealand.

Methods

A four-Phase modified Delphi method was employed to achieve consensus amongst Task Force members on the preferred operational definition of sarcopenia for use in Australia and New Zealand (Figure 1). The Delphi method supports the structuring of group communication to allow a group of individuals to, as a collective, deal with complex problems and reach consensus (21). The modified Delphi method (22) employed by the Task Force allowed for face-to-face communication in Phase 1 and approval of final statements in Phase 4. The Task Force leaders (GD, DS, JZ) designed and modified the questionnaires in Phases 2 and 3. The modified Delphi method used by the Australian and New Zealand Society for Sarcopenia and Frailty Research (ANZSSFR) Task Force adhered to preferred reporting methods and procedures (23).

Figure 1
Flow Chart of modified Delphi Method



ANZSSFR - Australian and New Zealand Society for Sarcopenia and Frailty Research. 2RQ – Second-round Questionnaire. 3RQ – Third-round Questionnaire. n = number of respondents

Selection of Task Force members

A group of individuals with an interest or expertise in sarcopenia (physicians, geriatricians, primary and post-doctoral researchers, allied health professionals, health service managers) were invited to participate in a focus group discussion and form a Task Force to achieve consensus on the operational definition of sarcopenia in Australia and New Zealand. Prior to the first meeting, participants were provided with an overview, background, aims, strategies and 17 key references related to the different operational definitions of sarcopenia (Appendix 2).

Phase 1 – Face-to-face meeting

On November 26th, 2017 following the ANZSSFR Scientific Meeting in Adelaide, Australia, 19 of the 24 invited Task Force members met for a four-hour meeting. Two presentations were delivered by researchers to the Task Force (DS and EMR) who summarized the key issues and outlined the agenda. Two focus groups were formed with key discussion points including whether the Task Force should adopt an existing definition or establish a new definition of sarcopenia, and to identify knowledge gaps in sarcopenia research. The de-identified minutes of the meeting are attached as Appendix 3 and informed the Second Round Questionnaire (2RQ).

Phase 2 – Online Questionnaire

On December 20th, 2017 an online, anonymous questionnaire (2RQ) developed by GD, DS and JZ was

circulated to 23 Task Force members. The minutes of Phase 1 were provided to Task Force members. The pre-specified level of agreement (80%) required for consensus was selected by the Task Force Leaders based on recommended practice (24, 25) and comparable modified Delphi studies (26). The methodology was outlined to Task Force members who were given three weeks to complete the 2RQ. A total of 12 questions and statements were contained in the 2RQ, which included four statements or key questions, four demographic questions and four free-text questions, attached as Appendix 4. The findings of the 2RQ informed the development of the Third Round Questionnaire (3RQ).

Phase 3 – Online Questionnaire

On February 26th, 2018 an online, anonymous questionnaire (3RQ) informed by the 2RQ and developed by GD, DS and JZ was circulated to 24 Task Force members who were given three weeks to complete the 3RQ. The results of the 2RQ were provided verbatim to Task Force members. A total of three statements and questions and four demographic questions were included in the 3RQ (Appendix 5).

Phase 4 – Circulation of position paper

The results of the 3RQ were provided verbatim to Task Force members. The statements and questions accepted to the pre-specified level of agreement in Phases 2 and 3 were circulated amongst Task Force members. Task Force members were requested to vote on a single statement contained within the position paper.

Statistical Analysis

Statistical analysis was undertaken using the pre-specified level of agreement (>80%) required to accept a statement. Statements or questions that did not reach a level of agreement greater than 80% but achieved moderate agreement (70-80%) in 2RQ were re-examined in 3RQ, consistent with comparable modified Delphi methodologies (26). Due to the size of the Task Force in addition to the small number of questions and statements being examined, investigation of dispersion or heterogeneity was not undertaken as is often performed in larger modified Delphi method studies (26).

Results

A total of 19/24 Task Force members participated in Phase 1. Due to one drop-out from Phase 1, 23 Task Force members were surveyed in Phase 2. In Phase 3, 24 individuals were surveyed following the re-joining of a Task Force member. Response rates in Phases 2 (n=17, 73.9%) and 3 (n=18, 75.0%) were similar. Due to de-identification, it is unknown whether there was consistency in responding Task Force members in Phases 2 and 3. The demographic details of participating Task Force members in Phases 2 and 3 are illustrated in Table 1.

In total, two statements regarding the operational definition of sarcopenia were accepted to a level greater than 80% and five were rejected (28.6% acceptance rate). Questions, statements and respective levels of agreement in each Phase are listed in Table 2. In Phase 2, 94.1% of respondents agreed that "an existing operational definition for sarcopenia should be adopted and validated using existing Australian and New Zealand data sets." Agreement on a preferred definition of sarcopenia was moderate in Phase 2, with 70.6% of respondents supporting the EWGSOP definition (1), 17.6% supporting the Foundation for the National Institute of Health Biomarkers Consortium Sarcopenia Project (FNIH) definition (16), and 11.8% supporting other (13) or new definitions. Consensus was not achieved (76.5%) on the adoption and promotion of the sarcopenia screening tool, SARC-F (27), for use by primary care clinicians.

Table 1
Demographics of Task Force members in Phases 2 and 3

Variable	Phase 2 (n = 17)	Phase 3 (n = 18)
Mean age, years (SD)	42.5 (10.3)	44.2 (10.2)
Gender, n (Female, %)	5 (29.4%)	6 (33.3%)
State or Country (n)		
New South Wales	1	1
Victoria	10	10
Queensland	1	1
South Australia	2	2
Western Australia	1	3
New Zealand	1	1
Position or Role (n)		
Primary clinical researcher	7	10
Post-doctoral researcher	2	2
Physician/geriatrician	5	4
Allied health	1	1
Health service manager	2	1

SD = Standard Deviation

In Phase 3, 94.4% of respondents agreed to adopt the EWGSOP operational definition of sarcopenia. Consensus was not achieved on whether the ANZSSFR should adopt and promote the accepted operational definition in its current form, including established cut-points, or await validation studies among Australian and New Zealand populations. There was moderate agreement (72.2%) amongst respondents that an established definition should be adopted and promoted immediately, with cut-points for sarcopenia components (e.g. muscle mass, muscle strength and gait speed) modified should future validation studies suggest this is necessary for Australian and New Zealand populations. Conversely, 22.2% of respondents agreed that the promotion of an established

Table 2
Non-free text questions, statements and respective levels of agreement

Questions and Statements	Respondents, n (% of invitation)	Agreement (%)	Outcome
Phase 2			
5. An existing operational definition for sarcopenia should be adopted and validated using existing Australian and New Zealand data sets	17 (73.9%)	94.1%	Accepted
6. If the adoption of an existing definition is the majority opinion of the Task Force, which operational definition of sarcopenia do you prefer?			
• EWGSOP	12 (52.2%)	70.6%	Informed 3RQ
• FNIH	3 (13.0%)	17.7%	
• Other	2 (8.7%)	11.8%	
8. If the ANZSSFR proposes to develop a new definition with Aus./NZ data on the basis of these survey results, please provide suggestions for the proposed methodology (eg. Measurement tools; cut-points etc.).			
• I do not support an additional definition therefore do not wish to comment	9 (39.2%)	52.9%	Rejected
• Preferred methodology / cut-points	8 (34.8%)	47.1%	
9. Should the society consider recommending the SARC-F as a screening tool for GPs, allied health and other health professionals?			
• Yes	13 (56.5%)	76.5%	Informed 3RQ
• No	4 (17.4%)	23.5%	
Phase 3			
5. Which operational definition of sarcopenia should the ANZSSFR adopt?			
• EWGSOP	17 (70.1%)	94.4%	Accepted EWGSOP
• FNIH	1 (4.2%)	5.6%	
6. The ANZSSFR should;			
• Adopt and promote an established definition in its entirety (including its existing cut-points)	1 (4.2%)	5.6%	Informed Phase 4
• Adopt and promote an established definition and modify this in future if subsequent validation studies suggest different cut-points are more appropriate in Australia and New Zealand	13 (54.2%)	72.2%	
• Await the validation studies of Aus./NZ cohorts prior to adopting and promoting a definition	4 (16.7%)	22.2%	
7. The pre-specified level of agreement (80%) was not reached to adopt the SARC-F as a recommendation for a screening tool for GPs and other allied health professionals (77%). To further explore this question, should the ANZSSFR;			
• Recommend the SARC-F as a screening tool for GPs, allied health and other health professionals at the present time	6 (25%)	33.3%	Rejected
• Not include SARC-F in its recommendations at the present time	1 (94.2%)	5.6%	
• Consider SARC-F in the future when consensus is achieved on the preferred operational definition of sarcopenia, and research is undertaken to demonstrate that SARC-F is an acceptable screening tool in Aus./NZ	11 (45.8%)	61.1%	
Phase 4			
1. The ANZSSFR Task Force should promote the EWGSOP definition in our activities directed at clinicians and researchers. However, a key objective for the Task Force in future will be to establish appropriate cut-points for appendicular lean muscle mass, handgrip strength and gait speed in Australian and New Zealand populations using data from local cohort studies.	23 (95.8%)	100.0%	Accepted

definition should await validation studies, while 5.6% of respondents agreed that an existing definition including cut-points should be adopted and promoted in its entirety without need for further validation among Australian and New Zealand populations.

In Phase 4, Task Force members were presented with a position paper and surveyed on their agreement with the statement posed in 3RQ, that the ANZSSFR should adopt and promote the EWGSOP and its established cut-points and modify these cut-points if validation studies suggest this as necessary. There was 100% agreement from 23 respondents to this statement.

Discussion

To date, a definition of sarcopenia has not been specifically developed for, or validated in, Australian and New Zealand populations. Across the globe, demographic differences have resulted in various measurement cut-points (17), therefore the ANZSSFR Task Force on Sarcopenia was formed to achieve

consensus on an operational definition of sarcopenia for use by researchers and clinicians in Australia and New Zealand. Leading researchers in sarcopenia have called for a consensus definition (20), a sentiment echoed in Phase 1 of the Delphi method undertaken by the Task Force. Task Force members achieved consensus in Phase 2 of the Delphi method to adopt and validate an existing definition of sarcopenia, rather than develop a new definition in Australia and New Zealand. The consensus to adopt the EWGSOP operational definition of sarcopenia reflects the fact that this is currently the most cited definition of sarcopenia worldwide (1).

While consensus was achieved on the adoption of the EWGSOP operational definition of sarcopenia, the timing of when to promote the definition fell short of the pre-specified level of agreement in Phase 3. A majority of respondents (72.2%) in Phase 3 agreed that the EWGSOP definition should be promoted immediately and subsequent validation studies should determine whether diagnostic cut-points need to be modified. Consensus on this statement was achieved in Phase 4 with agreement of 100%. Therefore the ANZSSFR Task Force have achieved consensus for the immediate promotion of the EWGSOP definition in its activities directed at researchers and clinicians. A key objective for the Task Force will be to determine whether appropriate cut-points for muscle mass, handgrip strength and gait speed can be established using data from local cohort studies if the EWGSOP cut-points are found not to be predictive of sarcopenia-related outcomes in Australian and New Zealand older adult populations (1). Australia and New Zealand are comprised of ethnically diverse, indigenous and immigrant populations to whom existing sarcopenia definitions and cut-points may not apply. The Asian Working Group on Sarcopenia previously adopted modified cut-points for the EWGSOP definition reflective of differences in muscle mass and strength observed between Asian and European older adults (18). Our Task Force will also promote sarcopenia research in Australia and New Zealand's diverse populations to determine whether different cut-points are required in different ethnic groups within our countries. Further, if these validation studies or further research in sarcopenia suggest other measures of muscle mass, muscle strength and physical performance are superior to those adopted, additional examination of the definition by the Task Force may be required.

In clinical practice, diagnostic tools such as dual energy X-ray absorptiometry (DXA), bioimpedance analysis (BIA) and handgrip strength dynamometers may not be immediately available to the clinician. A screening tool for sarcopenia, SARC-F, was developed for use by clinicians and was found to be valid for predicting adverse outcomes in sarcopenia (27). A recent meta-analysis demonstrated that the SARC-F had poor sensitivity but high specificity for predicting those that should undergo further diagnostic testing for sarcopenia (28). While the majority (61.1%) of respondents reported a decision should be made on the use of SARC-F following further research, only 33.3% supported the immediate adoption and promotion of this tool for use as a screening device in the Australia and New Zealand. Therefore, the Task Force will advocate for further research on SARC-F in Australia and New Zealand and re-evaluate support for the SARC-F as a screening tool in the future.

A Delphi method may be limited by the breadth and diversity of its participants and rate of responses. In this modified Delphi method, a broad range of Task Force members across Australia and New Zealand were involved, however this process was limited by low or no representation from some Australian states. This Delphi method was strengthened by response rates in Phases 2, 3 and 4 exceeding 70% and the release of results verbatim to Task Force members. While preference exists for the involvement of patients or consumers in a Delphi method (23), the complexity and depth of knowledge required to judiciously answer questions and statements required experts in the field of sarcopenia, particularly given the low levels of public awareness of sarcopenia. Nevertheless, future activities for this Task Force will seek to engage clinicians and consumers.

The development of this consensus definition has the potential to unify researchers across Australia and New Zealand and assist with further international collaborations. In addition, the provision of a consistent definition and message to primary care clinicians and the aged care and long-term care sectors, where prevalence is at its highest, may increase diagnosis and treatment of sarcopenia.

Conclusion

The ANZSSFR will adopt and promote the EWGSOP operational definition of sarcopenia in Australia and New Zealand however the ANZSSFR acknowledges further research is required to validate the definition in this setting. This is a significant step towards regional and international consensus on sarcopenia in the understanding of this disease. Validation studies will be undertaken using this definition among specific regional and ethnic populations, and may result in future recommendations which provide adapted cut-points for individual components of sarcopenia. Any future variations to the current EWGSOP definition will be considered and evaluated by the ANZSSFR Task Force prior to adoption and validation.

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Declarations: Within the last five years, RV has attended advisory or consensus meetings, received grants and honorarium as well as presented for Nestle, Nutricia and Abbott.

Conflict of interest: There are no conflicts of interests to declare.

Ethics statement: Ethics approval was not required for this study. Each participant met the required contribution standards for authorship. This process was consistent with comparable Delphi method studies that include professionals only.

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