An international consensus statement on the methodological standards for physical activity and sedentary behaviour guidelines development

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ABSTRACT

Background: The World Health Organization and many national health bodies have released physical activity and sedentary behaviour guidelines; however, there are inconsistencies across jurisdictions, which may partly be due to variation in guideline development processes. This study aimed to develop international consensus on the methodological standards for the development of future physical activity and sedentary behaviour guidelines.

Methods: We conducted a modified Delphi study. Experts in physical activity and/or guideline development rated a series of statements on stakeholder involvement, the types of evidence and study designs considered, and the utilisation of formal approaches in guideline development. Consensus was defined as group agreement of ≥80%.

Results: Twenty-three participants from eight countries reached consensus that 1) different stages of the guidelines development process require the involvement of different stakeholders; 2) previous study-level synthesised evidence must be included in evidence reviews and individual studies can be included if published after the most recent review or where review evidence is unavailable; 3) parallel randomised controlled studies must be included in review processes (83.3% agreement), with observational cohort studies marginally missing the agreement criterion (79.2% agreement), while predictive modelling, crossover trials, non-randomised trials and case control studies can be included; and 4) formal approaches must be utilised to assess the quality of individual primary studies, the reporting and quality of systematic reviews, and the overall process for grading evidence.

Conclusions: The findings provide a set of methodological standards to improve consistency and rigour in the development of future physical activity and sedentary behaviour guidelines.

INTRODUCTION

Physical activity is linked to a wide range of health outcomes throughout the life course. In children, being physically active is beneficial for muscle strength and fitness, cardiometabolic health, bone health, cognitive development, mental health, and reduced adiposity.[1] In adults, regular physical activity helps to prevent and manage noncommunicable diseases such as heart disease, stroke, diabetes, and several cancers, as well as improving cognitive health, mental health, and sleep.[1] Despite these benefits, large proportions of the child and adult population globally are insufficiently active.[2,3] As a result, physical inactivity is estimated to account for almost four million deaths each year[4] and costs the global economy an estimated US$27 billion annually.[5]

The World Health Organization (WHO) and national health bodies around the world have released physical activity guidelines, with many also covering sedentary behaviour. Despite significant overlap in the body of evidence reviewed, current recommendations differ across jurisdictions.[6] For example some sets of guidelines recommend a *minimum range* of 150 – 300 minutes of moderate intensity aerobic activity per week[1,7] whereas others recommend a *minimum threshold* of 150 minutes, without providing a recommended minimum range[8,9]. In addition, while most sets of guidelines have a general recommendation to minimize sedentary time without a specific quantitative threshold, the Canadian guidelines[9] specify a maximum limit of eight hours per day, which includes no more than three hours of recreational screen time.

A recent review, undertaken to inform this work, highlighted variation in the quality of physical activity and sedentary behaviour guideline development processes, the types of

evidence considered, and how evidence was appraised.[6] For example, the number and types of stakeholders involved has differed across jurisdictions, there has been varied involvement of methodologists in the guideline development process, differences in the types of evidence considered, and varied use of formal approaches to assess the certainty of the evidence.[6] These differences may explain, at least in part, why different recommendations emerged.

Whilst methodological standards for guideline development have been produced by a range of reputable entities including the WHO[10], the Centers for Disease Control and Prevention in the USA[11], and the National Institute for Health and Care Excellence in the UK[12], these types of guidance documents are generic across topics and often do not specify details that may be particularly important for specific fields, for example the types of experts that should be involved in the guideline development process and the types of evidence that should be considered. Given the variation in the methods used to develop previous guidelines[6], more specific and standardized guidance may be beneficial in the field of physical activity and health.

To date, no systematic effort has been made to establish global standards for the development of physical activity and sedentary behaviour guidelines. In the absence of such standards, guideline developers are likely to continue to apply inconsistent approaches, predisposing inconsistencies in recommendations across jurisdictions due to methodological differences. Therefore, this study aimed to develop international consensus on the methodological standards applied to the development of future physical activity and sedentary behaviour guidelines.

METHODS

Study design

A modified Delphi study design was used.[13] The Delphi method is a structured approach to gaining consensus from experts or informed respondents that form a Delphi panel.[14] The respondents take part in sequential surveys, with each round refined based on feedback from the previous. After each round, the group responses are fed back to the panellists who can reconsider their views based on the opinions of the group.[14] The Delphi process involved three phases, as described below and summarised in Figure 1. The Conducting and REporting of DElphi Studies (CREDES) guidelines were followed.[15]

Phase 1 – Development of the study protocol

The authorship group designed and oversaw the Delphi process. KM and ES have experience in the development of national and/or global physical activity and sedentary behaviour guidelines, RC is a Grading of Recommendations, Assessment, Development, and Evaluations (GRADE)[16] methodologist, and AP and CLH have expertise in the conduct of Delphi processes. A narrative review of the processes used to develop global and national physical activity and sedentary behaviour guidelines was undertaken.[6] This review highlighted variation in stakeholder involvement, the types of evidence considered, the types of study designs included in the evidence reviews, and the use of formal evidence appraisal processes. Thus, these four issues informed the structure of the initial Delphi survey.

Phase 2 – Panel selection

Using the combined knowledge of the authorship/steering group, we developed a list of 61 potential participants. This list included leading scientists in the health effects of physical activity and sedentary behaviour, those who have led previous physical activity and sedentary behaviour guideline development processes, and methodological experts in public health guideline development. We sought to ensure that the invited participants reflected both gender and geographic diversity. We sent a preliminary email to potential participants to describe the aim of the study, followed by a formal invitation to participate in round one, including links to the participant information sheet, consent form, and initial survey. A target of a minimum of 20 experts was set to form the expert panel.[17]

Phase 3 – Consensus process

Surveys were administered online using NOVI Survey (https://novisurvey.net/). We adopted a respondent only approach, whereby only those who responded to each round were invited to participate in subsequent rounds. The Delphi process was coordinated by AP, who reported the results back to the wider steering group.

Round 1

After completing a brief questionnaire on area(s) of expertise and previous involvement in guideline development, the expert panel were asked to rate 31 statements on a scale of 0 (not important) to 10 (extremely important) (see supplementary file 1). The survey included four sections: 1) Who should be involved in the development of physical activity and sedentary behaviour guidelines? 2) What types of evidence should be considered in the review process? 3) What types of study designs should be included in the evidence review process? and 4) What aspects of guideline development should utilise formal approaches?

In addition, we invited open comments for each statement and encouraged both supportive and critical feedback. The expert panel were informed that an *a priori* threshold median value of ≥7 would make a statement eligible for inclusion. The steering group calculated median values, interquartile range (IQR) to assess whether a statement should be included, and quartile deviation (QD) to define level of agreement (>1.0 = low, >0.6 - 1.0 = medium or ⩽0.6 = high),[18] and collated and discussed qualitative comments to inform round two. A summary of the round one feedback, without the use of specific statistics to avoid the bandwagon effect (the majority opinion leading people to adopt the majority view), was circulated to participants one week prior to sending the round two survey.[19]

Round 2

The design of round two was informed by the results of round one. Qualitative comments from section one (Who should be involved in the development of physical activity and sedentary behaviour guidelines?) indicated that the question was too broad, as it was felt that different stakeholders were required for different stages of the guideline development process. The section one question was therefore reformatted to 'Who should be involved in what elements of physical activity and sedentary behaviour guidelines development?'. This enabled participants to score whether each stakeholder group should be involved in 1) the review of the evidence; 2) the production of guideline recommendations; 3) the development of the messaging to target audiences; and 4) the dissemination of guidelines. In round two, participants were asked to rate 40 section one statements on a scale of 0 (not important) to 10 (extremely important).

For sections two to four, 'must be' (median ≥7 high-moderate QD), 'can be' (median ≥7 low QD), or 'should not be' (median <7) statements were created for each element voted on in round one. This prioritisation method ensured that as well as defining the essential elements of the guideline development process, the consensus process also identified elements that should be excluded.[20,21] Participants were asked to vote on whether they agreed or disagreed with 19 statements. We used percent agreement to define consensus,[18] with an *a priori* threshold of ≥80% agreement making an element eligible for inclusion. If a participant disagreed with a statement, they were asked to define what they felt it should be and justify why. We disseminated a summary of the round two findings one week before the third-round survey. We presented quantitative results for those elements that were defined as finalised and provided written justification.

Round 3

The third round predominantly focused on finalising section one (Who should be involved in what elements of physical activity and sedentary behaviour guidelines development?). Forty prioritisation statements were created for stakeholder groups that 'must be', 'can be', and 'should not be' included in each stage of the guideline development process. In addition, based on the round two quantitative results and qualitative feedback, the steering group felt one question related to section two (What types of evidence should be considered in the review process?) required further clarification from the expert panel. In round two the panel were asked to confirm that individual original studies should not be considered in the review process. The feedback indicated that as a general rule guidelines should be informed by review level evidence, however it was felt that individual original studies could be considered if they were published after the most recent systematic review or meta-

analysis, or when there was no systematic review level evidence available. Therefore, a further question related to original studies that were published after the most recent systematic review or meta-analysis, or when there was no systematic review level evidence available was added to the round three survey. The panel were asked to vote on whether they agreed or disagreed with all statements in round three. The expert panel were informed that an *a priori* threshold of ≥80% agreement would make an element eligible for inclusion. If a participant disagreed with a statement, they were asked to define what they felt it should be and justify why.

Ethical approval was granted by Edinburgh Napier University, School of Health and Social Care Research Integrity Committee (SHSC3054564).

RESULTS

Of the 61 experts invited to take part, 27 (44%) consented and completed round one. Of these, 24 (89% of round 1 respondents) completed round two, and of these, 23 (96% of round 2 respondents) completed round three. Participants resided in eight countries (Table 1). In total, 20 participants in round one (74%) reported having prior involvement in physical activity guidelines development (Table 1).

Table 1. Participant characteristics

	Invitees (n=61)	Round 1 (n=27)	Round 2 (n=24)	Round 3 (n=23)
Country of residence, n (%)				
Australia	14 (22.9)	5 (18.5)	3 (12.5)	3 (13.0)
Canada	5 (8.2)	5 (18.5)	5 (20.8)	5 (21.7)
Colombia	1 (1.6)	1 (3.7)	1 (4.2)	1 (4.3)
Denmark	4 (6.6)	4 (14.8)	4 (16.7)	4 (17.4)
Ireland	2 (3.3)	2 (7.4)	1 (4.2)	1 (4.3)
Lebanon	1 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)
Netherlands	1 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)
Norway	1 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)
Switzerland	2 (3.3)	1 (3.7)	1 (4.2)	0 (0.0)
United Kingdom	12 (19.7)	6 (22.2)	6 (25.0)	6 (26.1)
United States	18 (29.5)	2 (7.4)	2 (8.3)	2 (8.7)
Not stated		1 (3.7)	1 (4.2)	1 (4.3)
Previous involvement in physical activity guidelines development, n (%)				
Yes		20 (74.1)	20 (83.3)	19 (82.6)
No		7 (25.9)	4 (16.7)	4 (17.4)

Round 1

For section one (Who should be involved in the development of physical activity and sedentary behaviour guidelines?), eight stakeholder groups scored a median ≥7 (supplementary file 2). With the exception of academics/researchers, for which QD indicated high agreement, there were low agreement levels for all stakeholder groups

(supplementary file 2). When these results were combined with the qualitative comments (all of which are included in supplementary file 3), it was apparent that the guideline development process needed to be separated into four areas to better delineate stakeholder group involvement - evidence review, production of guideline recommendations, development of messaging, and dissemination of guidelines.

For section two (What types of evidence should be considered?), a median score of ≥7 was obtained for four evidence types (supplementary file 2). Agreement, as assessed by QD, ranged from high to low (supplementary file 2). For section three (What types of study designs should be included in the evidence review?), a median score of ≥7 was obtained for eight study designs, with a QD agreement range of low to moderate (supplementary file 2). For section four (What aspects of guideline development should utilise formal approaches?), all statements scored ≥9. Agreement across all statements was moderate (supplementary file 2).

Round 2

Participants in round two rated the importance of 40 statements about stakeholder involvement in guidelines development (section one) and were asked to rate whether they agreed or disagreed with 19 statements about the type of evidence to be considered (section two), study designs to be included (section three) and approaches to appraising the evidence (section four).

For section one, four stakeholder groups scored ≥7 for involvement in the evidence review, five scored ≥7 for involvement in the production of guideline recommendations, five scored

≥7 for involvement in the development of the messaging, and six scored ≥7 for involvement in dissemination of the guidelines (supplementary file 4).

For sections two to four, ≥80% agreement was achieved that previous study-level synthesised evidence *must be* considered in the review process. The panel failed to reach consensus on the inclusion of previous review-level synthesised evidence ('umbrella reviews' or 'review of reviews') and previous or new participant level synthesised evidence. The panel expressed concerns that umbrella reviews may not take into consideration the quality of the underlying primary research and may lose important detail and/or mask the granularity needed to make specific recommendations (supplementary file 3). For previous or new participant level synthesised evidence, some experts felt these were valuable, some felt the level of subjective decision making in the 'preparatory phase' of the data analysis posed uncertainty over their usefulness, and others stated that they were insufficiently familiar with this type of evidence to make an informed judgement (supplementary file 3). One evidence type (individual original studies) required further consideration in round three with an updated statement.

Agreement of ≥80% was reached that parallel group RCTs *must be* considered. There was 79.2% agreement that prospective cohort studies *must be* considered, falling just short of our threshold for consensus, with the remaining experts suggesting that prospective cohort studies *can be* included. The qualitative feedback indicated strong agreement for the inclusion of prospective cohort studies, as it is the most common type of evidence available and *"is largely the only way to get hard endpoint data"* (supplementary file 3). Consensus was reached that a range of other study designs *can be* considered in the review process

including predictive modelling, crossover trials, non-randomised trials and case control studies. There were mixed views on the inclusion of cross-sectional evidence; some respondents expressed that cross-sectional studies should be avoided *"in all circumstances/for all outcomes"*, whereas others felt cross-sectional data *"can provide important information"* particularly in the absence of stronger types of evidence (supplementary file 3).

Consensus was reached that formal approaches *must be* utilised in all aspects of guideline development, including the assessment of the quality of primary studies, the reporting of the quality of systematic reviews, and the overall process for grading evidence (table 2). However, the qualitative data revealed concerns over whether the available tools are fit for purpose (supplementary file 3).

Table 2. Consensus for the types of evidence and study designs to be considered, and the use of formal approaches to the appraisal of evidence

Guideline development area		% agreement
Types of evidence to be considered in the review process	***Must be* included**	
	Previous study-level synthesised evidence	**95.8**
	***Can be* included**	
	Individual original studies*	**91.3**
	Previous review-level synthesised evidence[1]	75.0
	Previous or new participant level synthesised evidence[2]	66.7
	***Must be* included**	

Types of study designs to be included in the evidence review process	Parallel group RCTs	**83.3**
	Prospective cohort studies[3]	79.2
	***Can be* included**	
	Predictive modelling	**87.5**
	Crossover trials	**83.3**
	Non-randomised trials	**83.3**
	Case Control studies	**83.3**
	Qualitative studies[4]	79.2
	Cost-effectiveness analyses[5]	79.2
	***Should not be* included**	
	Cross-sectional studies[6]	62.5
	Other study designs (e.g., pre-post design)[7]	58.3
Utilisation of formal approaches in guideline development	**Formal approach *must be* utilised**	
	The assessment of the quality of RCTs	**95.8**
	The assessment of the quality of observational studies	**95.8**
	The assessment of the quality of reporting of systematic reviews	**95.8**
	The assessment of the quality of systematic reviews	**91.7**
	The overall process for grading evidence	**87.5**

Legend: *consensus achieved in round 3; next most popular answer where consensus was not reached: [1]must be 12.5%; [2] must be 29.1%; [3]can be 20.8%; [4]must be 12.5%; [5]must be 12.5%; [6]can be 37.5%; [7]can be 37.5%.

Round 3

For the updated statement on the inclusion of individual original studies – if they have been published since the most recent systematic review or meta-analysis or there was no

systematic review level evidence available – 91.3% of participants agreed (table 2). The main focus for round three was for participants to vote on whether they agreed or disagreed with 40 statements about the inclusion of stakeholder groups in the four stages of guideline development; 30 statements met the ≥80% threshold of consensus (table 3).

Table 3. Consensus for stakeholder involvement in stages of the guideline development process

Stage of the guideline development process		% agreement
Evidence review	***Must be* involved**	
	Academics/researchers	**100.0**
	Evidence synthesis/guideline development methodologists	**100.0**
	***Can be* involved**	
	Other methodologists	**100.0**
	Librarians	**100.0**
	***Should not be* involved**	
	General public	**95.7**
	Government/policy makers	**95.7**
	Funders	**95.7**
	Communication experts	**91.3**
	Target populations of sub-recommendations[1]	78.3

	Healthcare professionals[2]	65.2
Production of guideline recommendations	***Can be* involved**	
	Healthcare professionals	**95.7**
	Evidence synthesis/guideline development methodologists	**91.3**
	Communication experts	**87.0**
	Target populations of sub-recommendations [3]	78.3
	Academics/researchers[4]	69.6
	***Should not be* involved**	
	Librarians	**95.7**
	Government/policy makers	**91.3**
	Funders	**87.0**
	Other methodologists	**87.0**
	General public	78.3
Development of the messaging	***Must be* involved**	
	Communication experts	**100.0**
	***Can be* involved**	
	Healthcare professionals	**100.0**
	General public	**82.6**
	Academics/researchers[5]	73.9
	Target populations of sub-recommendations [6]	73.9
	***Should not be* involved**	
	Librarians	**95.7**
	Other methodologists	**95.7**

	Funders	**87.0**
	Evidence synthesis/guideline development methodologists	**87.0**
	Government/policy makers[7]	78.3
Dissemination of the guidelines	***Must be* involved**	
	Communication experts	**100.0**
	***Can be* involved**	
	Target populations of sub-recommendations	**91.3**
	Funders	**91.3**
	Healthcare professionals	**87.0**
	Academics/researchers	**87.0**
	Government/policy makers[8]	73.9
	***Should not be* involved**	
	Librarians	**91.3**
	Other methodologists	**87.0**
	Evidence synthesis/guideline development methodologists	**87.0**
	General public[9]	56.5

Legend: next most popular answer where consensus was not reached: [1]must be 13.0%; [2]can be 30.4%; [3]must be 13.0%; [4]must be 30.4%; [5]must be 26.1%; [6]must be 26.1%; [7]can be 17.4%; [8]must be 21.7%; [9] can be 34.7%.

DISCUSSION

This study sought to establish international consensus on the methodological standards applied to the development of physical activity and sedentary behaviour guidelines. This covered four key aspects of guideline development: 1) Who should be involved? 2) What

types of evidence should be considered? 3) What types of study designs should be included? and 4) What aspects of guideline development should utilise formal approaches?

The expert group felt that different stakeholders should be involved in different stages of the guideline development process. In terms of the evidence reviews, there was unanimous agreement that both academics/researchers and evidence synthesis/guideline development methodologists *must be* involved. However, a recent review of physical activity and sedentary behaviour guidelines development processes found that over half did not involve a methodologist.[6] The reasons for this are unclear but may include: a lack of awareness that the involvement of a methodologist is recommended; a lack of access to relevant methodological experts; a perception that the guideline development group had sufficient methodological expertise; budgetary constraints; or national guideline development protocols not requiring the inclusion of a methodologist.

The messaging of guidelines is critical for ensuring they are understood by, and resonate with, the intended target audience. The panel unanimously agreed that communication experts *must be* involved in both the development of the messaging and the dissemination of guidelines. However, to date this has not been common practice.[22] In recent years a framework has been developed to guide the communication of global and national physical activity guidelines[22] and greater emphasis has begun to be placed on this element. For example, for the Canadian 24-hour movement guidelines, published in 2020, a knowledge translation team was established, who undertook quantitative and qualitative research to determine the optimal communication channels and messages to be used.[23,24]

Consensus was reached that previous study-level synthesised evidence *must be* included in the review process and individual original studies *can be* included if they have been published since the most recent systematic review or meta-analysis or there was no systematic review level evidence available. The panel failed to reach consensus on the inclusion of previous review-level synthesised evidence ('umbrella reviews' or 'review of reviews'). One possible explanation for this is that such reviews often include a range of study designs, posing challenges for disentangling the evidence from different study types. Regardless, major guidelines in the field, including those from the WHO[1], the USA[7] and Canada[9], have relied heavily on umbrella reviews. Following recommended processes (e.g. [10-12]), guideline development is a complex, costly, and time-consuming undertaking, thus pragmatic decisions must be made; requiring guideline development groups to appraise individual reviews in areas where umbrella reviews are available is likely not practical. If umbrella reviews continue to be used, however, they should adhere to methodological standards (e.g. [25,26]) and may require guideline developers to conduct more in-depth examination of selected, particularly relevant, or higher quality individual reviews.

The only study design that the expert panel agreed *must be* considered in the review process was RCTs. The inclusion of observational cohort studies in the *must be* considered category marginally missed the criterion for consensus (79.2% agreement). Given the nature of the evidence on physical activity and health, prospective cohort studies are the main study design underpinning current guidelines and are likely to remain a key source of evidence to inform future guidelines. It was therefore surprising not to reach consensus on the inclusion of this type of evidence.

To ensure public health guidelines are credible and valid, a rigorous development process should be followed. This is the first study to establish methodological standards for the development of physical activity and sedentary behaviour guidelines. Such standards are particularly important for the field of physical activity and health given current differences in guidelines across jurisdictions, variation in the quality of previous guideline development processes, and the predominance of evidence from observational studies.[6] It should be acknowledged, however, that many jurisdictions have existing protocols that must be followed in the development of public health guidelines, some of which may not include all aspects that were covered in this Delphi study. There may be barriers to incorporating the proposed standards, such as resources and time. However, incorporating as many aspects as possible, alongside national protocols and/or the use of generic guideline development standards, may help to improve both consistency and rigour in the development of future physical activity and sedentary behaviour guidelines. Adopting or adapting existing guidelines, such as those produced by the WHO, is another potential approach to streamlining the process, reducing duplication, and improving the consistency of guidelines across jurisdictions.

The Delphi method provided a formal approach to establish consensus on acceptable methodological standards, not only on the processes required to develop guidelines on this topic, but on the typology of evidence that should be used to inform future physical activity and sedentary behaviour guidelines. This approach, or similar approaches, may have utility in other areas of public health guideline development, where subject specific guidance may also be beneficial. Applying this approach to other public health guideline topics would also

be useful to inform how the types of experts and types of evidence considered necessary or appropriate for guideline development may vary.

Strengths of this work include the criteria to select the expert panel, recruitment of a sufficient sample size to allow for response stability within multiple rounds,[27] good retention of participants,[28] the use of a pre-defined protocol including an *a priori* threshold for inclusion, the use of quartile deviation (level of consensus) rather than simply relying on measures of central tendency, and the appointment of an expert in Delphi methods to oversee the collection and reporting of the findings. However, some limitations should be acknowledged. Over half the invited experts declined our invitation to take part, which limited our sample size and potentially diversity in opinions; however, our target of a minimum of 20 experts was met. Almost all respondents were based in high-income countries. Although our sample was largely reflective of the geographic spread of experts in physical activity guidelines development, the panel may have been relatively homogenous in terms of demographics and cultural perspectives. Therefore, the consensus reached in this study may not necessarily reflect the views of those residing in low- and middle-income countries. We applied an *a priori* threshold for consensus, which is considered good practice, but using a more, or less, stringent threshold would have impacted the findings. Another limitation is that we did not address some aspects of the guideline development process, including the volume and/or quality of evidence considered sufficient to inform guidelines, although published standards for evaluating evidence already exist, for example GRADE.[16]

CONCLUSION

This is the first study to establish methodological standards for the development of physical activity and sedentary behaviour guidelines. We reached consensus on the range of stakeholders that should be involved in different stages of the guideline development process, the types of evidence and study designs that should be considered, and the aspects of guideline development that should utilise formal approaches. Applying this set of methodological standards may help to improve both consistency and rigour in the development of future physical activity and sedentary behaviour guidelines.

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Competing interests

ES is a paid consultant and holds equity in Complement Theory Inc, a US-based company whose products and services relate to physical activity. All other authors disclose no conflict of interest for this work.

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