

The National Osteoporosis Foundation's methods and processes for developing position statements

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Abstract

Summary The methods and processes described in this manuscript have been approved and adopted by the NOF Board of Trustees on November 11, 2015. This manuscript has been peer-reviewed by the NOF Research Committee and *Osteoporosis International*.

The National Osteoporosis Foundation frequently publishes position statements for the benefit of educating healthcare professionals and the general public on a particular issue and/or concern related to preventing osteoporosis and/or promoting strong bones throughout the lifespan. This manuscript represents the official methods and processes adopted by the NOF Board of Trustees for the purpose developing future position statements in a transparent and unbiased manner.

Keywords Position statement · Process · National Osteoporosis Foundation

Abbreviations

AHRQ Agency for Healthcare Research and Quality
NOF National Osteoporosis Foundation
NIH National Institutes of Health

Introduction

The National Osteoporosis Foundation (NOF) frequently publishes position statements for the benefit of educating healthcare professionals and the general public on a particular issue and/or concern related to preventing osteoporosis and/or promoting strong bones throughout the lifespan. A position statement is an explanation, justification, and/or recommendation that is reflective of NOF's stance on a particular issue at the time of publication. The purpose of this manuscript is to outline the organization's internal methods and processes for

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developing future position statements in a transparent and unbiased manner. NOF's goal is to ensure that necessary checks-and-balances are in place so that all position statements reflect only evidence-based scientific research, eliminating any opportunity for bias, or the perception of bias. To accomplish this goal, NOF attests that all position statements on behalf of the organization

1. Conform to the process outlined in this document throughout the entirety of the project
2. Be based on an external evidence review which shall be published alongside or in advance of the position statement in the same peer-reviewed journal
3. Cite this manuscript in the methodology section of each position statement
4. Fully disclose all potential conflicts of interest of authors and/or the organization
5. Be subject to a minimum 14-day public comment period
6. Remain completely free of bias from the funding source and/or other interest groups
7. Publicly disclose the underlying methods and processes

NOF position statements should not be relied upon as an independent basis for action, but rather as a reliable resource for evidence-based information on any given topic. NOF's basic elements of process are modeled from the 2009 Institute of Medicine (IOM) report on *Conflict of Interest in Medical Research, Education, and Practice* [1], as well as the methods and processes of the US Preventive Services Task Force [2] and ACCME Standards for Commercial Support [3].

Definitions

Position statement

A position statement is an explanation, a justification, or recommendation for a topic of emerging importance that reflects NOF's stance regarding the concern. NOF position statements are based on a published evidence report(s) and authored by an expert panel. Position statements undergo a 14-day public comment period, are subject to peer-review by the NOF Research Committee, and meet the requirements of the journal in which it is published. Position statements reflect current scientific evidence at the time of publication and may be updated and/or discontinued at any time as deemed appropriate by the NOF Research Committee.

Expert panel

The expert panel is a group of individuals representing a broad range of disciplines, appointed by the NOF Research

Committee to author NOF position statements on behalf of the organization. An expert panel may have as few as three and a maximum of ten members and one chairman. Members of the expert panel do not receive financial compensation and have no knowledge of any funding source (if present) until the position statement has been accepted by a peer-reviewed journal for publication. Members of the expert panel are appointed on the basis of the qualifications outlined below and the current needs of NOF for particular areas of expertise:

1. Knowledge and experience in the critical evaluation of research published in peer-reviewed literature and in the methods of evidence review
2. Understanding and experience in the application of synthesized evidence to clinical decision-making and/or policy
3. Expertise in prevention and/or treatment of osteoporosis

Strongest consideration is given to individuals who are recognized nationally or internationally for scientific leadership within their fields of expertise. It is expected that each expert panel be diverse in regard to the academic backgrounds, areas of expertise, and traits such as gender, race, and ethnicity of the members.

Evidence report

The evidence report is an independently generated and published systematic review and synthesis of the current peer-reviewed scientific literature, which serves as the basis for the development of NOF position statements. These reports may also be used for informing and developing coverage decisions, quality measures, educational materials and tools, clinical practice guidelines, and research agendas. The evidence report will be used to inform the expert panel prior to or during the development of a position statement. Multiple evidence reports, including those published by authoritative scientific bodies such as the National Academies of Sciences, NIH or AHRQ, may be utilized in drafting a position statement.

Evidence review team

The evidence review team is an independent internal or external group contracted by NOF, or an authoritative scientific body such as the National Academies of Science (NAS) or AHRQ, to conduct a systematic review(s) of specified questions concerning the evidence on prioritized topics. Members of the evidence review team must submit to NOF a conflict of interest disclosure form for review prior to beginning their work on the evidence report. Examples of independent evidence review teams in which NOF may contract include, but are not limited to, the following:

- US Agency for Healthcare Research and Quality Evidence-Based Practice Centers
- Public or private universities
- Reputable consulting groups

The evidence review team may consult with the expert panel initially to seek help defining/refining the question for which the literature search will support, and to advise the expert panel of outcomes from the evidence report. The expert panel may seek explanation or further understanding around a specific outcome in the evidence report but shall refrain from inserting any personal scientific opinions or bias that may influence the evidence review team.

Staff

Those individuals employed by NOF. This does not include the evidence review team who may receive compensation from NOF for their work.

Conflict of interest

A conflict of interest is “a conflict between private interests and the official responsibilities of a person in a position of trust.” A conflict of interest thus arises when a person has to play one set of interests against another [4]. Conflicts of interest are defined as follows:

- Prior research in the area within 2 years
- Acceptance of funds to support research in the area
- Appointment to scientific or corporate boards
- Acceptance of consulting fees, honoraria, etc.

Outside funding and conflicts of interest management

External funding

The NOF may accept external funding (i.e., industry, other not-for-profits, etc.) to support the development or update of an evidence report by an internal or external body (e.g., a university, consulting group, or etc.) who is blinded from the original funder until the final evidence report has been submitted to NOF (funding source will be recognized in the evidence report prior to publication). Evidence reports may be funded through a restricted account within the organization (for evidence reports developed without outside funding) or the NOF general research fund.

Development of NOF position statements, derived in part or whole from an evidence report(s), must be solely supported

through the NOF general research fund and free of outside funding.

NOF will maintain full accounting records for a minimum of 7 years after completion of the project as per NOF record retention policy to document how funds for each individual project are allocated and/or distributed.

Members of both the evidence review team and the expert panel shall be blinded of any outside funding of any evidence report until both manuscripts have been submitted to NOF for publication in the peer-reviewed journal.

Fundraising for specific projects

NOF will abide by all procedures as outlined in the organization’s procedures manual in regard to acceptance of industry funds. Funds raised for a specific project shall be blinded to members of the evidence review team and expert panel (this excludes any NOF science staff) until the manuscript(s) are submitted to NOF for publication in a peer-reviewed journal. The NOF Research Committee is responsible for the determining the appropriateness of any particular topic for publication of a position statement prior to acceptance of any external funding.

Individual conflicts of interest

Less than 50 % of the evidence review team and/or expert panel may have significant conflicts of interest within the past two calendar years. The chair of the expert panel and/or primary author of the evidence report shall have no significant conflicts of interest upon appointment within the past two calendar years.

Declaration of conflicts of interest

All members of the expert panel shall declare in writing all potential conflicts of interest in accordance with ACCME standards [3] at the beginning of the project. Declaration statements will be reviewed prior to appointment, and all potential conflicts of interest will be resolved in accordance with ACCME standards and mechanisms for the resolution of conflicts of interest. If a potential conflict of interest arises during the process of developing any position statement, that individual shall disclose the conflict of interest to NOF immediately. Conflicts of interest arising during the process of developing a position statement do not preclude an individual from the expert panel. However, in the instance where the expert panel chair or primary author of the evidence report encounters a significant conflict of interest during the development process, a new chair primary author free of conflicts of interest will be appointed. The former chair of an expert panel encountering a significant conflict of interest during the development process may remain a member of the expert panel so long as the

conflict is transparently disclosed in a timely fashion to NOF. A former primary author encountering a significant conflict of interest during the development process may remain part of the author team so long as the conflict is transparently disclosed in a timely fashion to NOF. The NOF Research Committee may at their discretion by a majority vote remove any member of an expert panel or evidence review team due to the lack of disclosing a significant conflict of interest and/or if a member is found to be engaging in any unfair or inappropriate act that may affect an outcome or the scientific integrity of the NOF.

Statement of financial support

All evidence reports will declare all financial support. The following statement will be included in the Acknowledgements section of all external financially supported evidence reports:

- “This research was partially supported by (*list funding source here*). However, the funding body(s) had no role in study design or conduct; study acquisition and data extraction, management, or analysis; interpretation of research findings; or the preparation, review, or approval of the manuscript.”

Assembly of position statements

Step 1: Topic nomination The NOF Research Committee of the Board of Trustees nominates topics for review by the public or internally. The public may nominate a topic via the NOF website (www.nof.org/positionstatements).

The NOF Research Committee of the Board of Trustees is responsible for approval of all proposed topics. The NOF Research Committee will evaluate topics based on the following criteria:

1. Contribution to addressing a current public health concern(s).
2. Topic represents a controversial source of consumer confusion or represents a professional need for clarification.
3. There is a sufficient scientific evidence base to allow the development of an evidence review and resultant position statement.

4. The proposed evidence review and position statement fit within NOF’s research priorities and mission.

Step 2: Development of a research plan and evidence report Once a topic has been approved, the NOF Research Committee is responsible for working with an independently contracted external evidence review team to develop a research plan that guides the evidence review process. This includes development of

1. Key questions
2. Eligibility criteria
3. Literature search strategy

NOF requires that all research plans (i.e., protocol) and extracted data be registered in PROSPERO (<http://www.crd.york.ac.uk/PROSPERO>), an international prospective register of systematic reviews. Once a draft evidence report is in the midst of becoming available, the NOF Research Committee may move forward in appointing an expert panel to author the position statement on behalf of the organization. The expert panel members also serve as internal peer-reviewers of the evidence report prior to its submission to the peer-reviewed journal.

Step 3: Assembly of expert panel The NOF Research Committee is responsible for appointing the expert panel to author the position statement according to the guidelines previously described. The NOF Research Committee is responsible for determining

1. The level of expertise and perspectives needed for the panel
2. Provide guidance on the length of the manuscript and approach to presenting the literature
3. Develop a timeline and milestones to accomplish the task
4. Identify external reviewers outside of the NOF Research Committee, if needed
5. Oversee the public comment period

Members of the NOF Research Committee may be appointed to the expert panel but must abstain from any committee decision-making and/or discussions involving the final position statement. Expert panel members may not be recommended as “suggested reviewers” during the journal’s review process.

Step 4: Expert panel assembly of draft position statement The panel is responsible for the evidence assessment and for authorship of the position statement.

The NOF Research Committee will provide guidance about the scope, timeline, literature review documentation, and anticipated length of the report to the expert panel. Generally, the elements of a position statement will include the purpose or intent, a concise review and assessment of the literature relevant to the subject, areas requiring more research, and an assessment of the overall strength and conviction of the recommendation(s).

At least one in-person meeting and/or a series of conference calls are anticipated. At its first meeting, the expert panel will

- Clarify expectations—review plan of work and task
- Agree on timeline and milestones
- Develop initial outline
- Assign tasks and/or subgroups

The expert panel will hold subsequent meetings or conference calls to

- Review progress
- Discuss and revise drafts
- Approve draft for review by the NOF Research Committee and public comment period

NOF utilizes the evidence grading system shown in Table 1. This system is similar to that used by prominent organizations such as the American Diabetes Association [5] or recommended by other experts [6]. The assigned grade reflects the totality of the evidence on a particular subject and was established by consensus of the expert panel. Expert panels are highly encouraged to reach scientific consensus in the position statement. In the instance scientific consensus cannot be reached, the chairman may move forward on any particular issue with 2/3 vote of approval from the expert panel members. The chairman and NOF staff will notify the NOF Research Committee and Board of Trustees of any instance(s) where full consensus has not been reached by the expert panel.

Members of the evidence review team (i.e., those producing the evidence report) shall review the draft position statement prior to submission to the NOF Research Committee to ensure consistency.

Step 5: NOF Research Committee review The goal of the review is to assure that the position statement is accurate and that the arguments in the

document support the findings of the evidence report and scientific literature. In keeping with that goal, the NOF Research Committee and any additional appointed reviewers will be asked to respond to the following questions in the review:

1. Is the task clearly described in the paper? Is the task fully addressed? Do the authors go beyond their task or expertise?
2. Are the findings, conclusions, and recommendations adequately supported in the paper by the evidence and arguments presented in the evidence report?
3. Is the organization easy to follow? Is the tone impartial?
4. What significant improvements, if any, might be made in the report? Please distinguish major and minor concerns/suggestions.

Staff will act as the liaison to the expert panel and the NOF Research Committee. The expert panel is expected to respond to the NOF Research Committee review, either by modifying the paper or explaining why no change is merited. When the NOF Research Committee chair is satisfied that comments have been addressed (changed or rationale for why no change), the paper will be published online for public comment. If the expert panel has not reached scientific consensus in one or more areas, the NOF Research Committee may decide by majority vote to (1) move forward with publication of the position statement, (2) revise the key questions and/or scope of the position statement, and (3) retract the decision for NOF to publish an official position statement.

Step 6: Public comment period NOF will impose a minimum 14-day public comment period for each position statement prior to its submission to a peer-reviewed journal. The NOF membership and/or other key stakeholder

Table 1 Evidence grading system

Level of evidence ^a	Description
A: Strong	Clear evidence from at least one large, well-conducted, generalizable RCT that is adequately powered with a large effect size and is free of bias or other concerns OR Clear evidence from multiple RCTs or many controlled trials that may have few limitations related to bias, measurement imprecision, inconsistent results, or other concerns
B: Moderate	Evidence obtained from multiple, well-designed, conducted, and controlled prospective cohort studies that have used adequate and relevant measurements and that gave similar results from different populations OR Evidence obtained from a well-conducted meta-analysis of prospective cohort studies from different populations
C: Limited	Evidence obtained from multiple prospective cohort studies from diverse populations that have limitations related to bias, measurement imprecision, or inconsistent results or have other concerns OR Evidence from only one well-designed prospective study with few limitations OR Evidence from multiple well-designed and conducted cross-sectional or case-controlled studies that have very few limitations that could invalidate the results from diverse populations OR Evidence from a meta-analysis that has design limitations
D: Inadequate	Evidence from studies that have one or more major methodologic flaws or many minor methodologic flaws that result in low confidence in the effect estimate OR Insufficient data to support a hypothesis OR Evidence derived from clinical experience, historical studies (before and after), or uncontrolled descriptive studies or case reports

RCT randomized controlled trial

^a Refers to the body of evidence

groups will be notified electronically about the public comment period. Comments from the public will be taken into consideration by the expert panel and shared with the NOF Research Committee. The final version of the position statement with any tracked changes arising from the public comment period will be sent to the NOF Research Committee chair at least 1 week in advance of submission to the NOF Board of Trustees.

Step 7: NOF Board of Trustees approval After the public comment period has closed and any necessary changes have been made, the final position statement will be sent to the NOF Board of Trustees for approval. The NOF Board of Trustees will seek endorsement from the NOF Research Committee

chair prior to its approval of the final position statement.

from the NOF website after 5 years or when a replacement document is forwarded by an organization and endorsed by NOF, whichever comes first.

Compliance with ethical standards

Sources of financial support None

Conflicts of interest TCW is employed by the National Osteoporosis Foundation. Bauer DC, Gagel RF, Greenspan SL, Lappe JM, LeBoff MS, Recker RR, Saag KG, and Singer AJ are members of the National Osteoporosis Foundation Board of Trustees.

Collaboration with external organizations

NOF may publish a position statement in collaboration with other 501(c)(3) not-for-profit associations. Collaborating bodies must adhere to the policies set forth within this guidance document. NOF will seek to have representation on any position statement produced by an external organization. If this is not possible, any position statement will be reviewed by the relevant NOF committee and their recommendation presented to the NOF Board for approval or disapproval. Evidence reports and position statements may be published in another society's peer-reviewed journal, as determined appropriate by the NOF Research Committee.

Endorsement of external position statements

NOF endorses documents developed by other not-for-profit organizations. These documents are reviewed by the NOF Research Committee and staff prior to their endorsement by NOF. Although there is agreement with the general concepts of these documents and confidence in the methodology used for development by the convening organizations, NOF may not agree with every identified statement and/or specific wording. These documents are not published by NOF and do not represent official NOF policy. Documents are removed

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