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ISPOR Report

Criteria and Process for Initiating and Developing an ISPOR Good Practices Task Force Report

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ABSTRACT

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR)'s "Good Practices Task Force" reports are highly cited, multistakeholder perspective expert guidance reports that reflect international standards for health economics and outcomes research (HEOR) and their use in healthcare decision making. In this report, we discuss the criteria, development, and evaluation/consensus review and approval process for initiating a task force. The rationale for a task force must include a justification, including why this good practice guidance is important and its potential impact on the scientific community. The criteria include: (1) necessity (why is this task force required?); (2) a methodology-oriented focus (focus on research methods, approaches, analysis, interpretation, and dissemination); (3) relevance (to ISPOR's mission and its members); (4) durability over time; (5) broad applicability; and 6) an evidence-based approach. In addition, the proposal must be a priority specifically for ISPOR.

These reports are valuable to researchers, academics, students, health technology assessors, medical technology developers and service providers, those working in other commercial entities, regulators, and payers. These stakeholder perspectives are represented in task force membership to ensure the report's overall usefulness and relevance to the global ISPOR membership. We hope that this discussion will bring transparency to the process of initiating, approving, and producing these task force reports and encourage participation from a diverse range of experts within and outside ISPOR.

Keywords: emerging good practices, good measurement practices, good practices, good practices for outcomes research, good reporting practices, good research practices, international standards task force, task force report.

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Introduction

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR)'s "Good Practices Task Force" reports (an umbrella term that includes "ISPOR Good Research Practices," "Good Practices for Outcomes Research," "Emerging Good Practices," and "Principles of Good Practice Task Force" reports but is distinct from "ISPOR Special Task Forces") are highly cited, multistakeholder perspective expert consensus guidance reports that reflect international standards for health economics and outcomes research (HEOR) and their use in healthcare decision making (see Appendix 1 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2020.03.001). These reports are designed to provide reference and guidance to the HEOR community regarding state-of-the-art methods for the topic of interest. By explaining how to generate and use evidence more effectively and efficiently, the ultimate goal of a task force report is to improve the overall quality of HEOR and positively impact healthcare decisions (Box 1).

From 2003 through 2019, ISPOR has published more than 60 task force reports (see Appendix 2 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2020.03.001). These reports cover a number of methods, including patient preference measurements, the conduction of indirect treatment comparisons and network meta-analyses, observational studies, decision analytic modeling, economic evaluations, and clinical outcomes assessments, among others.

Despite the prominence and relevance of these task force reports to the HEOR field, many in the larger scientific community are unfamiliar with the process and criteria for proposing an ISPOR Good Practices Task Force and developing a task force report. Therefore the intent of this article is to explain task force proposal development, evaluation, recommendation, and final

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BOX 1. ISPOR Good Practices Task Forces: background and context.

ISPOR Good Practice Task Force activities are conducted under the auspices of the ISPOR Health Science Policy Council. This council, established in 2004 and reorganized in 2016 and 2017, advises the ISPOR Board of Directors on important scientific research and health policy issues in the health economics and outcomes research (HEOR) field. The Health Science Policy Council is global in representation. It is composed of ISPOR past presidents, Avedis Donabedian Outcomes Research Lifetime Achievement Award recipients, invited HEOR experts (members who have worked in senior positions with 15 or more years in the field, have noteworthy publication records, and provided significant service to the Society), members of the ISPOR Councils or Regional Consortia, and ISPOR's Chief and Associate Chief Science Officers (Chief Science Office).

The Health Science Policy Council has 4 primary objectives or responsibilities: (1) oversee task forces and special interest groups, including recommendations for approval of new groups; (2) suggest scientific and policy-related content for ISPOR conferences; (3) advise on and assist in scientific and policy-related initiatives and collaborations; and (4) produce white papers on selected strategic topics.

The Health Science Policy Council is divided into 3 committees to meet these objectives. The Policy Outlook Committee is responsible for policy-related initiatives or collaborations with other organizations and white papers (eg, developing the ISPOR Value Assessment Frameworks). The Science/Research Committee oversees the ISPOR Special Interest Groups, and the Task Force Review Committee (comprised primarily of methodologists) is responsible for evaluation of task force proposal submissions.

approval by the ISPOR Board of Directors. In addition, the steps to initiate the approved task force and the consensus review process that the respective task force report undergoes are described as well. Finally, we hope that this discussion will encourage participation from a diverse range of experts within and outside ISPOR.

ISPOR Good Practices Task Force Reports

The Good Practices Task Force reports support ISPOR's mission "to promote health economics and outcomes research excellence to improve decision making for health globally." These reports represent consensus guidance on the appropriate research methods, analysis, and reporting standards to conduct research to inform healthcare decisions and improve health. They provide specific recommendations on how to design and approach conducting research, how analyses should be performed, and how the results from health economics and outcomes research should be interpreted and disseminated. The reports are intended for practical, real-world application. In fact, many reports include checklists or tables that outline specific steps and the sequence in which these steps should be taken in the conduct of research (eg, in parallel versus sequentially). These reports address areas of agreement and issues where there are gaps or controversies that have not been resolved or integrated in the HEOR literature.

In the early 2000s, when the first task forces were undertaken, ISPOR membership was much smaller and the target audience for the reports was primarily researchers. These task forces focused on established HEOR methods to synthesize the literature and then current practice to develop ISPOR Good Research Practices Task Force reports (eg, ISPOR-SMDM Modeling Good Research Practices[1–7] and ISPOR Retrospective Database Analysis Good Research Practices[8–10]).

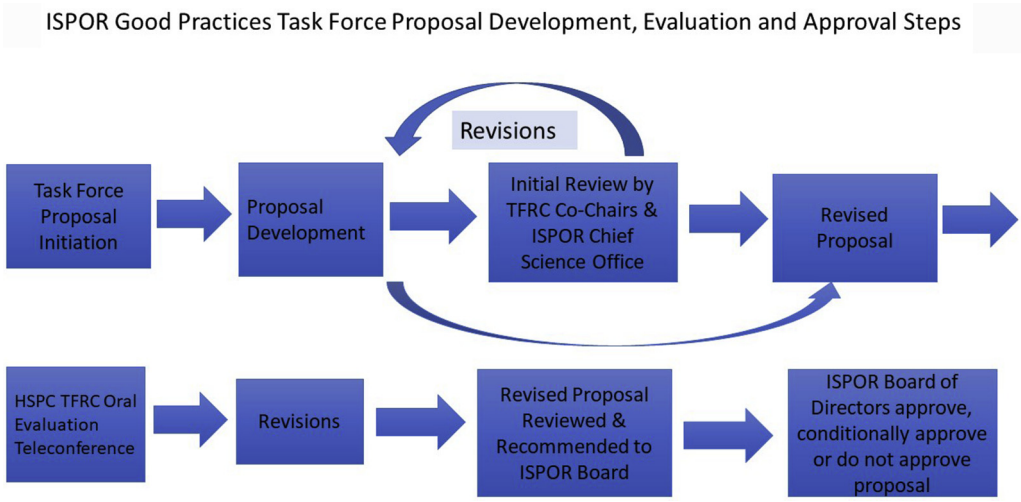
Although the aforementioned reports were developed and published simultaneously, the majority of task force reports are single publications or single reports that start a series of sequential companion publications. The subsequent reports typically tackle issues not previously addressed in the earlier report or in the literature. For example, the most cited task force report, ISPOR's "Principles of Good Practice on Translation and Cultural Adaptation Process for Patient-Reported Outcomes Measures,"[11] was published in 2005 and followed in 2009 by the multinational trials report,[12] which covered 3 specific topics where the authors felt more discussion of methods and good practices would be beneficial (eg, translations required for each country, the approach to use when the same language is spoken in more than one country and the methods to gather evidence to support the pooling of data collected using different language versions of the same tool). ISPOR has published 11 patient-reported outcomes or clinical outcomes assessment–focused task force reports that translate the US Food & Drug Administration's (FDA's) "Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims" into good practices with several more in development.[13]

As ISPOR's scope and membership have expanded, ISPOR has received requests from members for good practice development on established methods from other disciplines that have been applied to healthcare research. For example, conjoint analysis (commonly used in market research) is grounded in consumer theory and the psychology of choice. The first "ISPOR Good Research Practices for Conjoint Analysis Task Force" report,[14] published in 2011, provides guidance for the design and conduct of conjoint analysis in health applications based on stated preferences research methods, and the companion reports on experimental design[15] and statistical analysis[16] provide in-depth guidance on how to design these studies and how to analyze and interpret the results. The latter two differ in that they are more broadly based on discrete choice experiments, an approach that originated in econometrics. As interest developed over time in healthcare decision making specifically, ISPOR started developing this type of guidance, such as the reports on performance-based risk-sharing arrangements[17] in 2013 and multicriteria decision analysis[18,19] in 2016.

"Emerging Good Practice" Reports

With the emergence of new HEOR methods and types of outcomes assessments, ISPOR members proposed these kinds of topics for good practice task forces. For topics with little or no published guidance, the Society established the ISPOR Emerging Good Practices Task Forces to develop initial recommendations. Reports on emerging good practices are also used to identify issues that require additional evidence before a final guidance for good practices can be made. The first reports on emerging good practices were published in 2015 as "Dynamic Simulation Modeling Methods in Health Care Delivery Research."[20,21] The first report on emerging good practices in clinical outcome

Figure 1. ISPOR Health Science Policy Council structure.



assessments[22] was published in 2016 and was followed by a report on clinician-reported outcomes in 2017.[23]

Who Uses ISPOR Good Practices Task Force Reports

ISPOR's task force reports are valuable scientific and educational resources for ISPOR's stakeholders. Reports are freely available to download on ISPOR's website. Task force reports are designed to be useful to researchers, academics, students, health technology assessors, medical technology developers and service providers, those working in other commercial entities, regulators, and payers.

ISPOR Good Practices Task Force reports have been referenced internationally by regulators and health technology assessment (HTA) agencies. For example, the FDA recommended the "ISPOR Clinician-Reported Outcomes Emerging Good Practices Report"[23] and referenced 4 of ISPOR's patient-reported outcomes/clinical outcomes assessment Good Practices Task Force reports[11,24–26] in its "Patient-Focused Drug Development Public Workshop Guidance 3" discussion document: "Methods to Identify What is Important to Patients & Select, Develop or Modify Fit-for-Purpose Clinical Outcomes Assessments."[27]

The task force reports are used by health technology assessors and decision makers, including regulators and payers around the world. For example, a nonexhaustive search showed that the "Canadian Agency for Drugs and Technologies in Health (CADTH) Guidelines for the Economic Evaluation of Health Technologies" references 11 of ISPOR's reports.[28] Brazil's Ministry of Health's economic valuation guideline references 8 reports.[29] Germany's health technology assessor, Institute for Quality and Efficiency in Healthcare (IQWiG)'s "General Methods Guidance" ["Allgemeine Methoden"] references 7 reports.[30] The Haute Autorité de Santé (HAS), or French National Authority for Health, cites the decision analytic modeling[31] and the transferability of economic evaluations across jurisdictions reports[32] as methodological references in its guidelines on economic evaluation.[33]

Moreover, ISPOR's budget impact analysis (BIA) reports[34,35] were the primary guidance sources for the French budget impact guidelines.[36] The Netherlands' "National Health Care Institute (Zorginstituut Nederland [ZIN]) Guideline for Economic Evaluations in Healthcare" states that, "The BIA should be designed, conducted, and reported in accordance with the internationally accepted principles of ISPOR."[37] ZIN agency staff report using the transferability[32] and Consolidated Health Economic Evaluation Reporting Standards (CHEERS)[38] reports in their daily work. The European Network for Health Technology Assessment's (EUnetHTA) 2015 publication on therapeutic medical devices[39] references 3 reports, and its "Methods for Health Economic Evaluations: A Guideline Based on Current Practices in Europe"[40] referenced 14 task force reports.

ISPOR task force reports have also been referenced by other professional societies, including the Academy of Managed Care Pharmacy's "Format for Formulary Submissions v4.0,"[41] which cited 16 reports. Finally, organizations such as the National Institute for Health Research (NIHR) recommend ISPOR task force report guidance. In this case, the NIHR's journals library mandates completion of the CHEERS checklist[42] by authors of reports that contain a cost-effectiveness component or substantial economic evaluation.

Members of international regulatory and HTA bodies actively participate in the development of ISPOR Good Practices Task Force reports. Members of the FDA, European Medicines Agency (EMA), World Health Organization (WHO), The National Institute for Health and Care Excellence (NICE), IQWIG, ZIN, HAS, the Italian Medicines Agency, CADTH, Argentina's Institute for Clinical Effectiveness and Health Policy (IECS), and Colombia's Institute of Health Technology Assessment (IETS) have participated as coauthors and reviewers on multiple task force reports. Payer organizations (eg, Humana and Premera Blue Cross in the United States) have participated as well.

Guidance on Developing an ISPOR Good Practices Task Force

Initiation, Purpose, and Rationale

In most cases, task force proposals are initiated by one or more ISPOR members based on their own judgment of the need for expert guidance on a given topic. In some cases, members are informed by the topics that ISPOR, via its councils, conferences, or publications, has indicated as high importance and timeliness. The Health Science Policy Council Task Force Review Committee has established criteria for task force proposals and a proposal format

for initiators (see Appendix 3 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2020.03.001).

In addition to foundational information on the topic, a well-defined objective and a detailed outline of the proposed report should be contained in the proposal. The rationale for the proposal must include a justification outlining why this good practice guidance is important and its potential impact on the scientific community. The rationale should include the following criteria:

1. Necessity: Why is this task force required? What are the controversies, issues, or concerns the task force will address? It should be noted that proposals to update an *existing* task force report will be evaluated by the same criteria. The justification for an update must be clearly described just as in a new proposal.
2. Methodology-oriented focus: Inherent in ISPOR Good Practices Task Force reports is a focus on methods and approaches to conducting research to inform healthcare decisions and improve health. This includes not only the methods of conducting research, but also how analyses should be performed, as well as how the results of studies should be disseminated.
3. Relevance to ISPOR's mission and its members: The task force must be relevant to ISPOR's mission. Furthermore, the report should be of broad interest to ISPOR members.
4. Durability: The topic of interest should not be a passing trend. It should be able to stand the test of time.
5. Broader applicability: The task force should not focus on a particular product, technology, or program, but instead be applicable to a wide array of technologies, situations, and geographic areas. ISPOR is a global organization.
6. Evidence-based approach: The rationale should be supported by empirical studies that resolve or identify underlying uncertainty about research methods. The rationale should also discuss the implications of using different approaches to study the phenomena and the expected outcomes from the task force in terms of obtaining consensus or providing recommendations. If insufficient studies are available to resolve uncertainty for most issues facing the task force, then the emerging task force designation is appropriate.

The proposal format should include a bibliography of the relevant evidence that supports the need for the task force's formation. The proposal bibliography and the ISPOR Scientific Presentations Database, which includes ISPOR conference-released presentations, are good resources for identifying subject matter experts at either the active task force member (coauthor) or designated primary reviewer level.

Timeline for Submission and Evaluation Processes

Task force proposals can be submitted at any time of year by anyone, but once the proposal has been accepted for consideration, the initiators must become ISPOR members if they are not already. Generally, the process starts with 1 or 2 initiator(s) or an ISPOR group (eg, the HTA Council) contacting the ISPOR Scientific & Health Policy Initiatives department, Chief Science Office, or other ISPOR staff person. The initiators are put in contact with the ISPOR Health Science Policy Council Task Force Review Committee staff liaison. The Task Force Review Committee liaison explains the proposal process and works with the initiators throughout the process from proposal development to evaluation and, ultimately, approval.

In the early stages, the ISPOR Task Force Review Committee liaison provides feedback on proposal drafts for clarity, scope, and completeness. The liaison also provides insight on the task force's membership. Because this can be a challenging aspect for the initiators, details are provided in a subsequent section, as well as in the proposal format (see Appendix 2 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2020.03.001). It should be noted that task force members are subject matter experts invited by the initiators to participate. They do not need to be ISPOR members.

Steps in the Task Force Evaluation Process

During the proposal development process, the liaison works with the Task Force Review Committee co-chairs to manage the task force proposal evaluation. Once a proposal is ready for initial evaluation, the Task Force Review Committee co-chairs, along with the ISPOR Chief Science Office, review the content of the proposal based on the criteria for the task force proposals. If the initial review finds that more than minor revisions are needed, such as those clarifying methodology and scope, the initial comments or suggestions are shared with the initiators. The initiators then revise and resubmit the proposal. The revised proposal is sent to the rest of the Task Force Review Committee members, and a teleconference evaluation with the initiators is scheduled. When the initial review indicates minor revisions, the Task Force Review Committee co-chairs send the proposal directly to the rest of the Task Force Review Committee members.

If more expertise on the subject matter of the proposal is needed for the proposal evaluation, a member of the Health Science Policy Council or an invited outside subject matter expert is invited to review the proposal. The evaluation of the task force proposal is the responsibility of the Task Force Review Committee. When a task force is at the evaluation stage, all members of the Health Science Policy Council are notified so that members of the Policy Outlook or Science and Research committees may request a copy of the proposal to read or review to provide comments. If comments are received, they will be shared with the initiators during the oral evaluation.

Finally, there is no guarantee of ultimate acceptance of a task force proposal. Key elements leading to acceptance are the importance and timeliness of the general topic as judged by the Health Science Policy Council Task Force Review Committee in consultation with the ISPOR Chief Science Office, the creation of a full proposal based on the aforementioned guidelines, and responsiveness to comments from the Health Science Policy Council Task Force Review Committee.

These 2 evaluation rounds are instrumental in the development of a strong, well-considered, in-scope proposal. This upfront work has the additional benefit of making the report easier to write. Issues are raised early, and the initiators' thought process is clarified by addressing them. After the 2-round evaluation process, the Task Force Review Committee co-chairs evaluate the final modifications to the proposal. If the finalized proposal is accepted or conditionally accepted based on minor revisions, it is recommended by the Task Force Review Committee on behalf of the Health Science Policy Council to the ISPOR Board of Directors for approval. A notification to this effect is sent to the full Health Science Policy Council and the ISPOR Chief Science Office.

The next step is submission of the final proposal and a "Board Recommendation for Action" letter requesting approval for task force formation to the ISPOR Director of Governance. The ISPOR Board of Directors either approves the task force formation or conditionally approves it with revisions to the proposal. After approval by the Board, the initiators are notified, and the task force is officially established.

It should be noted that the task force proposal evaluation process, like the development process, is on a first come, first

BOX 2. Steps in the task force report consensus development process.

To ensure that all "ISPOR Good Practices Task Force" reports are of the highest quality, the reports undergo 2 formal rounds of review—on the first and final draft of the report. In addition, as part of the consensus development process, all ISPOR Good Practices Task Forces are required to present their findings and solicit input at the ISPOR Annual and European conferences. This rigorous process of multiple rounds of review ensures a global consensus with robust, evidence-based, and widely recognized recommendations.
Please note: Because of ISPOR conference dates, as well as task force progress, the order of the presentation and review process steps may change.

1. Task Force produces a first draft report.
2. An invitation to review is sent to the expert designated primary reviewers.
3. Coauthors consider all written comments* received and address as appropriate in revisions to the report. (No formal coauthor written response to reviewers is required.)
4. Coauthors present findings to date at the ISPOR Annual and/or ISPOR European conference.
5. The manuscript is sent to a medical editor after revisions from the first review round for clarity, editing, and proofreading.
6. Once the manuscript comes back from the medical editor and any issues are addressed, the final draft is sent to all reviewers (interested ISPOR members that joined the task force review group and the designated primary reviewers). There is also an announcement in the ISPOR eBulletin when task force reports are under review.
7. Coauthors consider all written comments received in the final review and address as appropriate in revisions to the report. (Again, there is no formal coauthor written response to reviewers.)
8. Coauthors present their final recommendations at the ISPOR Annual and/or ISPOR European conference.
9. Coauthors meet in person during one or both of these conferences to discuss any outstanding issues, make revisions, and finalize the text.
10. Lead authors submit the final report to *Value in Health.*
    (Because of the extensive consensus development process, "ISPOR Good Practices Task Force" reports do not undergo peer review at the journal.)

*Reviewers submitting substantive written comments are acknowledged in the published report.

served basis. Nevertheless, owing to the rolling comments/revision process, multiple task force proposals are often under evaluation (or development) concurrently (Fig. 1).

How Task Forces Operate

Announcing the New Task Force

After approval by the Board of Directors, a task force webpage is added to the ISPOR website, listed under the Member Groups menu on the ISPOR homepage. The new task force is announced in the ISPOR eBulletin under the Scientific & Health Policy Initiatives section. In addition, it is mentioned in the next ISPOR Scientific & Health Policy Groups email that is sent quarterly to all active ISPOR members. In these communications, ISPOR members are invited to join the task force's review group.

Selection of Task Force Members and Designated Primary Reviewers

The initiator(s) will (co-)chair and lead the task force. The task force initiators are responsible for identifying and convening a limited, but engaged, number of international subject matter experts (approximately 10 members) to develop the task force report. Experts are identified based on an established track record of published research or presentations. Task force members actively involved in the development of the report are listed as coauthors. A task force member who chooses an advisory role or one who cannot actively participate may change his or her status to a designated primary reviewer and be acknowledged as such.

Ideally, task force members will represent a range of perspectives, geographic areas, and work environments (eg, academia, research organizations, government, regulatory agencies, payers, HTA bodies, and the life sciences industry). Diversity in perspective (with input from various geographies and areas of practice) is critical to develop high-quality, well-balanced, and widely applicable good practice standards. Other details regarding task force membership can be found in section 9 of the proposal format (see Appendix 2 in Supplemental Materials). Initiators of the task force proposal should provide justification for each task force member based on their experience and expertise in the area under consideration.

During the evaluation process, the Health Science Policy Council may recommend changes to meet the membership criteria and subject matter expertise. We suggest that the proposal initiators do not formally invite task force members until the proposal has been approved by the Health Science Policy Council because the evaluation process might identify other appropriate individuals if the membership criteria are not met. Task force membership is finalized when the Health Science Policy Council recommends the proposal to the ISPOR Board of Directors and the board approves it.

Designated primary reviewers

In addition to the active task force members, the task force initiators should identify at least 12 to 15 other subject matter experts to provide initial feedback on the draft report. These reviewers should be reflective of the international community and the stakeholders that will use the task force report. Designated primary reviewers are asked to critically evaluate the task force report for scientific rigor and to provide their insight on the topic to the task force members. All reviewers submitting substantive written comments are acknowledged in the publication. Designated primary reviewers do not need to be ISPOR members.

Other task force reviewers

Although designated primary reviewers are subject matter experts, knowledgeable ISPOR members are also encouraged to submit written comments during the formal review periods. They can join the task force's review group via the task force index page (under the "Member Groups" menu on the ISPOR homepage) or the task force's individual webpage or by responding to an invitation to review announcement in the ISPOR eBulletin or an ISPOR Scientific & Health Policy Groups email.

Review of the Task Force Report: Consensus Development Process

ISPOR Good Practices Task Force reports undergo 2 formal rounds of review—on the initial review and final draft of the report (Box 2). Reviewer comments improve these reports through requests for clarification, proposed suggestions, provision of other perspectives, and additional references. Furthermore, they ensure that ISPOR reports are thorough, reflect a multistakeholder perspective, are geographically applicable, and demonstrate a consensus of expert opinion. All reviewers submitting substantive written comments are acknowledged by name in the published report. Finally, as part of the consensus development process, all ISPOR Good Practices Task Forces are required to present the findings and solicit input at the ISPOR Annual and European conferences.

Task force reports do not undergo additional peer review at *Value in Health* owing to the aforementioned written and oral presentation review process. All members of the task force are responsible for reviewing, considering, and addressing, as appropriate, comments received before issuing the final report. Because of the multiple review process, the guidance from such reports results in robust, evidence-based, and widely acceptable recommendations for conducting high-quality research in health outcomes and related disciplines.

How Task Forces Work to Create the Report

An ISPOR Scientific & Health Policy Initiatives staff liaison will be assigned to assist the initiators (now task force co-chairs) with project management of the task force. Voluntary service on a task force is prestigious but can also be demanding. All task force members are expected to actively participate in all stages of report development, writing, reviewing, revising, and addressing comments, as well as attending monthly teleconferences for coauthorship. In addition, often task forces hold in-person meetings during ISPOR conferences.

As part of ISPOR's Code of Ethics,[43] all members of the task force are asked to share conflict of interest information at the beginning and the end of the process. Additional aspects of the Code of Ethics require all ISPOR members to refrain from publishing or presenting material related to any ISPOR group at any stage without coauthor consultation. Finally, agreement with the *Value in Health* publication statement that the ISPOR Code of Ethics was followed during development and publication of the report is required.

Dissemination of Good Practices Task Force Reports

ISPOR Task Force Good Practices reports are among the most cited articles in *Value in Health*; 25 are in *Value in Health's* top 50 most cited, with 7 in the top 10 (see Appendix 1 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2020.03.001). In addition to publications, these reports are disseminated to members through ISPOR conference workshops, issue panels, or forum presentations. Furthermore, many reports are presented as online webinars or developed into short courses held during ISPOR conferences.

Conclusion

ISPOR Good Practices Task Force reports are expert consensus guidelines that set international standards for health economics and outcomes research (clinical, economic, and patient-reported) and its use in healthcare decision making. They are an integral part of ISPOR's mission to improve healthcare decision making, and ultimately, global health. The Society believes that every healthcare decision should be informed by the best scientific research derived from rigorous, proven methodologies.

ISPOR encourages its members to contribute to ISPOR's research excellence by participating in task forces and reviewing task force reports. Member expertise and insight are critical to the high quality and consensus nature of these reports.

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Supplemental Material

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.jval.2020.03.001.

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