ISPOR Report

Opportunities and Barriers to the Development and Use of Open Source Health Economic Models: A Survey

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A B S T R A C T

Objectives: Health economic (HE) models are routinely used to support health policy and resource allocation decisions but are often considered "black boxes" that may be prone to error and bias. Open source models (OSMs) have been advocated to increase the transparency, credibility, and reuse of HE models. Previous studies have demonstrated interest in OSMs among the health economics and outcomes research community, but the number of OSMs remains low.

Methods: We conducted an online survey of ISPOR (the leading professional society for health economics and outcomes research) members' perspectives on the usefulness of OSMs and barriers to their development and implementation.

Results: Respondents (N = 230) included academics (27%), pharmaceutical (or related) industry representatives (23%), health research or consulting representatives (21%), governmental or nonprofit agency representatives (10%), and others (19%). Respondents were generally not familiar with barriers to the development and adoption of OSMs. Most agreed that OSMs would improve transparency (92%), efficiency (76%), and HE model reuse (86%) and promote confidence in using HE models (75%). The use of OSMs by health technology assessment authorities was considered a very important indicator of the usefulness of OSMs by 49% of respondents. Three-quarters of respondents perceived legal concerns and the ability to transfer data as important barriers to the development and use of OSMs.

Conclusions: Respondents believe that OSMs could increase the transparency, efficiency, and credibility of HE models, but that several barriers hamper their widespread adoption. Our results suggest that fundamental changes may be needed across the health economics and outcomes research community if OSMs are to become widely adopted.

Keywords: cost-effectiveness, models, open science, open source.

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Introduction

Health economic (HE) models, by which we mean decision-analytic cost-effectiveness and comparative effectiveness models, are widely used to inform health policy decisions.[1,2] HE models are mathematical models that rely on a variety of data inputs and assumptions, and their results are inherently uncertain.[1,3-6] It is common for HE models to be associated with a lack of transparency in their development and reporting.[7,8] This hampers the systematic assessment of their validity and quality and makes model replication challenging.[9,10] HE models may also be prone to error, which may be exacerbated by a lack of transparency.[11] These shortcomings have led decision makers and the public to question the credibility of HE models and to potentially distrust or misuse their results.[12-14]

Transparency is a hallmark of science, and its importance in HE modeling has been widely recognized,[7,8,13,15,16] yet the challenges are generalizable to disciplines beyond health sciences and decision modeling and relate to broader objectives of evidence-based

policy and decision making.[12,17] The development of open source models (OSMs), which stands at the center of the current debate in the health economics literature, may be part of the solution for achieving greater transparency.[18-21] In this context, we define OSMs as models that are fully disclosed and to which unrestricted access to the model source code (and use thereof) is granted. This increasing interest in OSMs has resulted in the development of platforms facilitating their dissemination.[22,23] Nevertheless, the number of available OSMs remains low.[24]

Some small studies have characterized a positive view concerning OSMs in the health economics and outcomes research (HEOR) community. An exploratory survey among 46 participants showed interest among the HEOR community for the use of OSMs, but that the number of OSMs found in the literature was limited.[18] More recently, 248 authors of cost-effectiveness analyses were invited to submit their models for inclusion in an open source repository, of which only 4 obliged.[20] These findings seem to highlight an incongruity between researchers' stated appetite for OSMs and their revealed willingness to support OSMs.

Owing to the small number of participants in previous research, it cannot be claimed that the views expressed represent the opinions of the broader HEOR community. Furthermore, there is a need to understand the factors that may explain the apparent mismatch in the supply and demand for OSMs.

We performed a survey among a broad sample of the HEOR community to elicit perceived barriers and opportunities regarding the development and use of OSMs in HEOR and decision making. These perspectives can be used to establish a research agenda and to determine which practical steps are required for the widespread development, implementation, and use of OSMs. The current research sought to elicit the HEOR community's views concerning the usefulness of OSMs, the barriers to the development and use of OSMs, and the worth of an interactive OSM repository.

Methods

Members of the Professional Society for Health Economics and Outcomes Research (ISPOR) OSMs Special Interest Group (SIG) designed a survey to assess the usefulness and barriers to the implementation of OSMs for HE analyses. The topics addressed in the survey were selected based on a consensus among leadership members of the SIG.

The survey included 2 questions relating to the occupational sector and familiarity with OSMs of respondents, 3 questions about (indicators of) the usefulness of OSMs, 1 question relating to barriers to the development of OSMs, 2 questions concerning the development of an interactive OSM repository, and 1 question on the importance of several topics that could be the focus of future SIG activities. At the end of the survey, respondents had the opportunity to leave any relevant comments in an open free-text field. The full survey is available in Appendix 1 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.10.001.

The ISPOR office circulated the survey to all ISPOR members (including SIG members) on May 18, 2020. A second request was distributed in 2 waves, on June 8, 2020, and June 11, 2020. A final reminder was sent on June 24, 2020. The survey was sent to at least 8236 ISPOR members (the total number of registered members varied at each time point).

All responses to the survey questions were formulated on a 5-point Likert scale (eg, very important, somewhat important, neutral, not very important, not at all important), except 2 questions concerning an interactive OSM repository and subjects for future events, which included an "Other" option that could be completed through free text. Results were summarized as the number and percent of respondents who selected each category of the scales.

Results

In total, 230 ISPOR members (3%) responded to the survey. A complete data set of anonymized responses to the closed questions is available in Appendix 2 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.10.001, and the free-text reactions to the open-ended questions are available in Appendix 3 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.10.001.

Leading affiliations reported by respondents included academia, pharmaceutical or medical device companies, and health research or consulting (Table 1). Most respondents were not at all or somewhat familiar with the technical specifications of OSMs (not familiar, 37%; somewhat familiar, 49%), the practical challenges for their development (35%; 48%), the secondary use of

Table 1. Primary occupation of respondents.

Primary occupation	n	%
Academia	62	27
Managed care//Pharmacy Benefit Manager	3	1
Clinical practice//hospital	10	4
Patient representative	0	0
Health research//consulting	48	21
Government//HTA agency//nonprofit	22	10
Industry//Pharmaceutical//Medical device//Diagnostic	54	23
Health care communications	2	1
Biotech	0	0
Student	18	8
Other	3	1
No answer	8	3
Total	230	100

HTA indicates health technology assessment.

existing OSMs (47%; 45%), and the barriers to their wider adoption (35%; 50%) (Fig. 1).

Concerning the usefulness of OSMs, most respondents agreed that OSMs would improve transparency in HE modeling, improve efficiency in healthcare modeling, facilitate model updating and recycling, and promote confidence in using HE models in decision making (Fig. 2). All specified indicators of the usefulness of OSMs for healthcare decision making were considered (very) important by most respondents (Fig. 3). More specifically, the requirement and use of OSMs by health technology assessment (HTA) authorities were considered to be a very important indicator of the usefulness of OSMs by 49% of respondents. All potential uses of OSMs mentioned in the survey were considered (very) important by the majority of respondents. The use of OSMs to increase the reliability of models, reduce redundancies and wastage of resources in evidence development, and support reimbursement decisions was considered as very important by, respectively, 52%, 48%, and 47% of the respondents (Fig. 4).

A total of 8 of the 11 barriers mentioned in the survey were considered somewhat or very important by at least 70% of the respondents. Respectively, 80%, 75%, and 74% of the respondents perceived the updatability of OSMs, legal concerns surrounding OSMs, and the ability to transfer underlying/related data (in a secure way to permit the execution of the model) as somewhat or very important barriers to the development and use of OSMs. Notably, the lack of a storage facility was considered a very or somewhat important barrier by only 50% of the respondents (Fig. 5).

Most respondents were favorable to the development of an interactive OSM repository. The 35 respondents who were unsure about the development of an interactive OSM repository and 7 respondents who were in favor did not answer the question relating to the importance of different reasons for developing such a repository. The ones who answered (N = 186) considered that increasing the availability of models (somewhat important, 32%; very important, 65%), facilitating the transaction and/or ability to procure the models (35%; 55%), and improving healthcare decision making (39%; 49%) were important reasons to develop an interactive OSM repository (Appendix Fig. 1 in Supplemental Materials

Figure 1. Familiarity of the respondents with different aspects of OSMs.
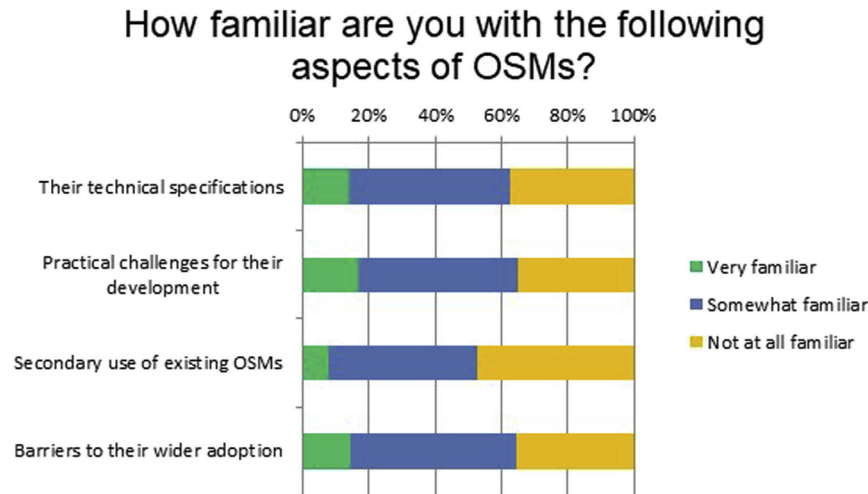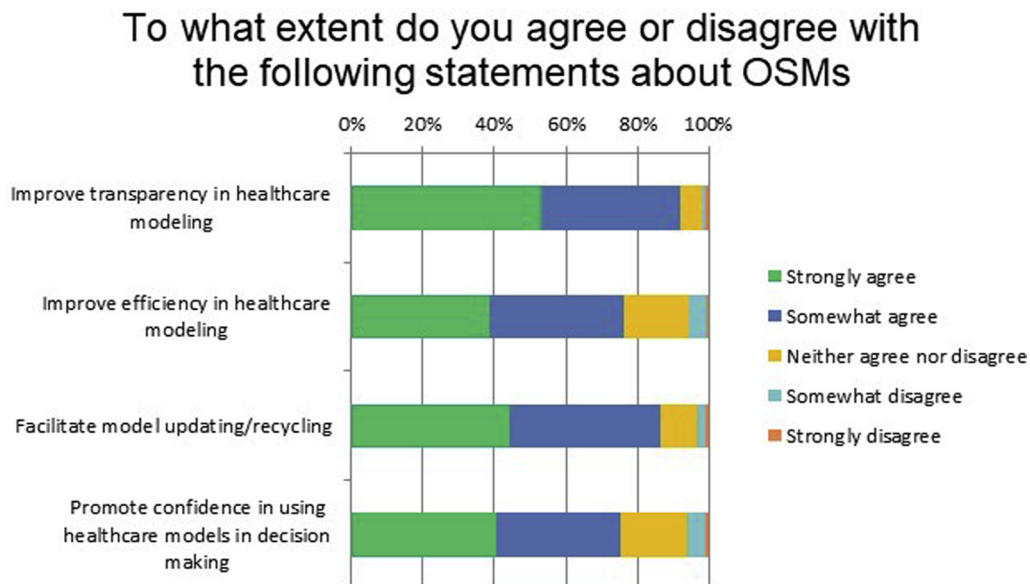

OSM indicates open source model.

found at https://doi.org/10.1016/j.jval.2021.10.001). Further advantages of an interactive OSM repository mentioned by the respondents in the free-text answers included that "It can be a great tool for teaching and autodidactic purposes," that it would increase the efficiency of research because one would know where to find OSMs, and that it may improve accountability and the "ability/accessibility for open source validation" (Appendix 2 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.10.001).

Finally, 222 respondents (97%) answered the question focusing on the importance of different issues raised in the survey, which could be addressed in further events organized by the OSM SIG. All but 2 of the 7 issues (ie, "Storage of OSMs" and "Remuneration to innovator") were considered as important by at least 70% of the respondents. The updatability of models and the use of multiple underlying data sources were the issues that were considered

somewhat or very important by 86% and 83% of the respondents. Issues concerning the confidentiality and security of OSMs (and the underlying data) and legal concerns surrounding the use of OSMs were considered somewhat or very important by 79% and 72% of respondents (Appendix Fig. 2 in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.10.001). Additional issues were raised in the free-text answers. Some respondents raised concerns about how to regulate the use of OSMs and prevent misuse of OSMs by third parties, who may update HE models, and how to ensure this is done appropriately. Other respondents highlighted the need to ensure that structural uncertainty is appropriately evaluated when using OSMs. There were also concerns about whether OSMs would actually increase the transparency of HE models.
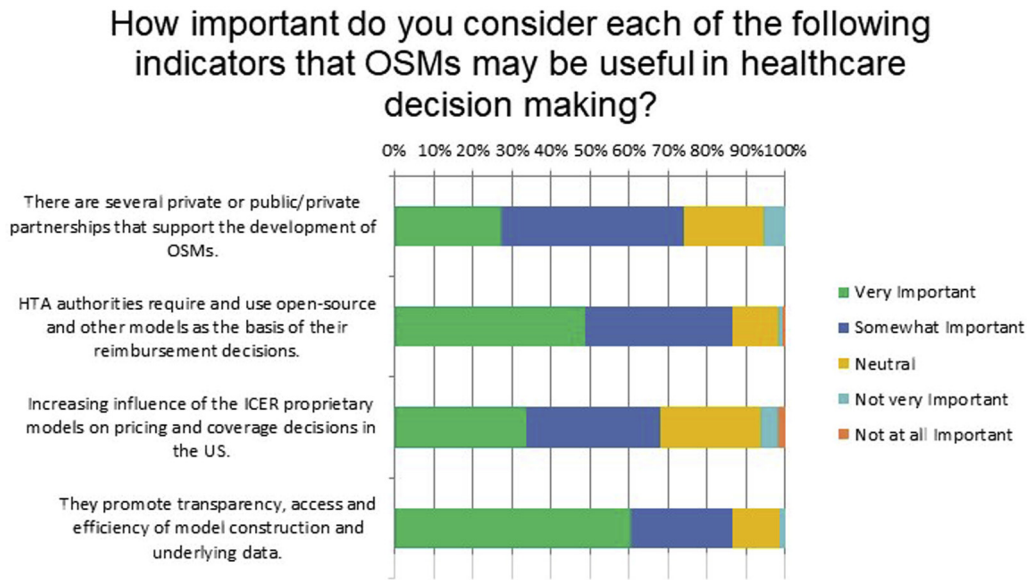
In their free-text answers (other topics or comments section), some respondents highlighted the importance of technical issues,

Figure 2. Usefulness of OSMs for healthcare decision making according to respondents.

OSM indicates open source model.

Figure 3. Indicators of the usefulness of OSMs.

HTA indicates health technology assessment; ICER, Institute for Clinical and Economic Review; OSM, open source model.

such as analysts' knowledge of the relevant online infrastructure to support OSMs. Others stressed the importance of the role of HTA agencies in promoting OSMs. Some respondents argued that OSMs may not, by definition, improve the quality and transparency of HE models. Others commented on the commercial aspects of OSMs. For instance, some respondents expressed their concerns regarding the potential commercialization of analysis scripts (code), leading to restriction of their (free) use. One respondent considered the potential impact of the widespread distribution of OSMs on the survival of nonacademic consulting companies. Another concern was that OSMs could lead to back-calculation of confidential price agreements. Alternative solutions to increase the transparency of HE models were also raised,

such as developing a "model design language that concisely but precisely describes a model" and standardizing modeling approaches (and deviations from it) within disease areas.

Discussion

Respondents agreed that there are numerous potential benefits associated with OSMs, including increased transparency, efficiency, and credibility. Respondents further agreed that the development and use of OSMs by HTA authorities would be an indicator of the usefulness of OSMs. Still, several barriers hamper the widespread adoption of OSMs, especially concerning their updatability, legal

Figure 4. Importance of the potential uses of OSMs.
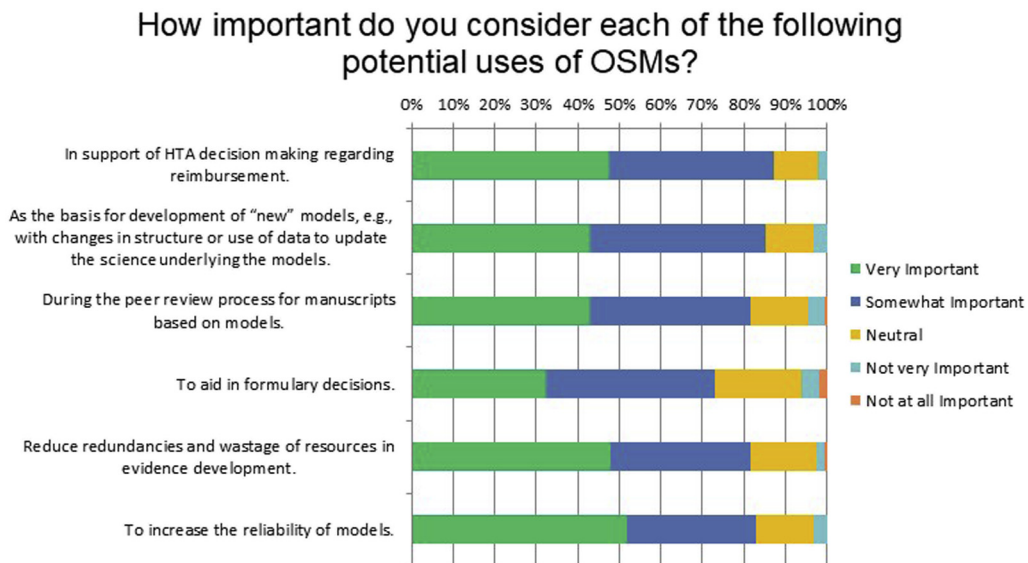
HTA indicates health technology assessment; OSM, open source model.

Figure 5. Importance of the potential barriers to the development and use of OSMs.

How important do you consider each of the following potential uses of OSMs?
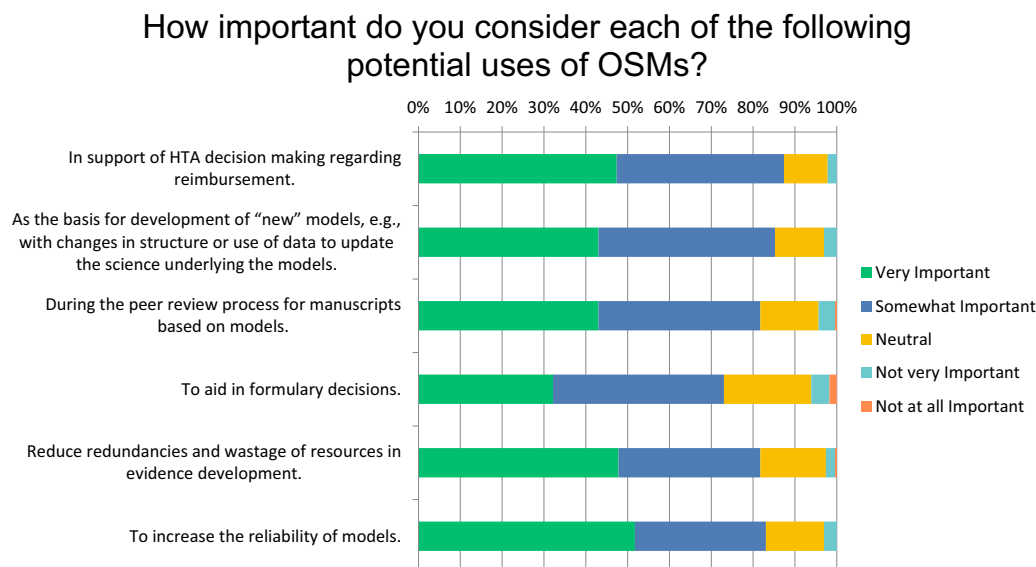
OSM indicates open source model.

concerns, and the sharing of confidential and person-identifiable data. The perceived need for careful consideration of the potential benefits and pitfalls of OSMs before their widespread implementation was nicely summarized by one respondent: "we need to get the basics right before pushing ahead with OS [open source]."

With high levels of support and low levels of uptake, it is important to understand barriers to the development and use of OSMs. An apparent lack of familiarity with OSMs among many respondents suggests a need for further education and capacity development in the technical aspects of OSMs. Groups such as the DARTH (Decision Analysis in R for Technologies in Health) work group[25] are already supporting this need by providing frameworks and recommendations for good coding practices specific to HE modeling.[26] Similarly, groups such as R for HTA are providing educational resources,[27] and there is a growing number of tutorial articles[28-30] and open source packages to make analyses more user friendly.[31,32] Familiarity with such tools and approaches may be a prerequisite for the wider adoption of OSMs.

Despite this lack of familiarity, there was almost no opposition to the development of an OSM repository. Only 2 of 230 respondents disagreed that developing an OSM repository was a good idea. Thus, there seems to be an untapped potential support for the further development of such initiatives. Our findings highlight a need for more effective communication around the use and barriers to adoption of OSMs. Actively seeking stakeholders' contributions during OSM development, as performed by the Open Source Value Project, may help to find appropriate solutions to these barriers.[33,34] Such initiatives are crucial in supporting the uptake, review, understanding, and reproducibility of OSMs.

The relative importance of legal concerns, the ability to transfer data, and issues relating to accessing and updating models suggest that external and infrastructural barriers are important. Contrary to this, a lack of storage facilities was not identified as important. Dedicated platforms for sharing OSMs do exist, such as the Open Source Model Clearinghouse[23] and the Peer Models Network,[22] yet, as demonstrated by Emerson et al,[20] uptake is low. These findings suggest that there is potentially appropriate infrastructure already available, but that the circumstances are not right for them to be useful.

Our survey findings suggest that the apparent disparity between support and adoption is in part because of a demand-side problem. That is, HTA agencies, regulators, and other end users of models do not require that models be made open source. Indeed, most respondents identified a lack of interest from decision makers as a key barrier. This is complemented by the finding that HTA and reimbursement decision making is seen as an important use case and that support from agencies such as the National Institute for Health and Care Excellence would be an important indicator of the usefulness of OSMs. This subject was repeatedly raised in free-text comments. Intervention by HTA agencies may be a sufficient condition for the promotion of OSMs to standard practice. As one respondent put it, "if they buy in then all will."

It is important to consider that the added value of OSMs for HTA agencies may be limited because, in general, agencies are granted full access to models or develop their own bespoke models under conditions of confidentiality. OSMs may be modified freely, but still require extensive review by HTA agencies. In this case, there may be no gains in either credibility or efficiency. Still, the almost unanimous support for OSMs indicates that their success could be guaranteed without top-down requirements. Creating an environment in which it is easier to develop and use OSMs could be key.

There were several limitations to our survey. The survey's response rate was low, but similar to other surveys of ISPOR members.[35,36] Although the sample size is large relative to similar studies, it is still too small to identify reliable and statistically significant differences in response frequencies. Furthermore, the sample may provide an over-representation of respondents more familiar with OSMs (including SIG members), although awareness levels were still quite low. Compared with the ISPOR membership, our sample included more academics (27% vs 12%) and health research/consulting employees (22% vs 16%), with fewer students (8% vs 18%) and employees from the pharmaceutical (and related) industries (24% vs 37%). Academics may be more likely to respond to any survey, or there may be greater interest in OSMs among academics, in which case involving other stakeholders might require more purposeful action to find adequate solutions to the identified barriers to the implementation of OSMs. Nevertheless, the overall high number of respondents compared with previous

research[18] and the broad distribution across sectors show that there is interest in OSMs across all stakeholder groups.

Although inherent in all surveys, a key limitation of our study is that we cannot be certain about how respondents interpreted terms used in the survey. In particular, the design of the survey did not enforce a relative interpretation of importance; respondents could, in principle, identify all items within a selection as being of equal importance. Matters such as "efficiency" in modeling and "legal concerns" may have been interpreted in a variety of ways. For instance, it is not clear whether respondents considered intellectual property rights when considering legal concerns. More generally, it is possible that respondents did not conceptualize OSMs consistently. It is important to distinguish between HE models, their application to decision problems, and their associated data, programs, and languages. Although we were only interested in HE models and any data required for their execution, it is possible that survey respondents interpreted our questions as relating to other aspects, such as clinical trial data. Furthermore, some important aspects were not included in the survey that, in hindsight, might have been. These include the importance of technical skills as a barrier to the adoption of OSMs and various commercial concerns that may arise from the availability of OSMs as applied to particular decision problems.

Nonetheless, our results suggest that fundamental changes may be needed across the HEOR community if OSMs are to become mainstream.[20] Further research concerning OSMs should focus on understanding incentives for all stakeholders to develop and use OSMs,[17] developing environments where OSMs (and their underlying data) may be shared securely, and how developing OSMs may influence work processes.[37] Here, a distinction between models (condition-specific templates or empty shells) and analyses (using these models) may be useful, given that the former may be made widely accessible to all whereas the results of the latter may be more restricted. Using such validated general-purpose models would increase both the comparability of analyses and the efficiency of performing them. Leveraging these benefits of OSMs requires developers to be more familiar with software engineering.

Developing uniform HE coding conventions and (dynamic) documentation guidelines for the dissemination of OSMs may increase their adoption by structuring the information flow concerning OSM development. It may further facilitate model review, reproducibility, and adaptability.[17,26,38] Of course, building OSMs is not an end goal. It is a means to achieve greater transparency, reuse, and reproducibility of HE models, but OSMs are likely not the only way forward, as mentioned by respondents. Alternative ways to promote these endeavors, including reporting guidelines, model registries, and other initiatives described elsewhere,[15] should also be championed. In addition, health economists should not reinvent the wheel and should make as much use as possible of available tools such as Github[39,40] to make their work more transparent and of experience from other fields where open source is more widely deployed. Even in an environment where OSMs become a standard approach to developing HE models, it does not prevent other issues from persisting, such as the potential publication bias in HE modeling.[41] Publication bias may be partly reduced by (compulsory) (pre)registration of HE evaluations and their protocols, as is required for clinical trials.[42-44]

Further research could focus on identifying (and creating) incentives to encourage developers to make their models open source. One such incentive may be the requirement of making model data and code accessible and reproducible by HEOR journals, as several scientific journals already do.[45,46] This would increase the transparency of analyses and could also improve their credibility. Another incentive could be to reward the efforts associated with open code development instead of solely rewarding publications. The findings of this survey will guide work to be undertaken by the ISPOR OSM SIG. By publishing the resulting data, we provide scope for further analysis. This may include subgroup analyses according to people's familiarity with OSMs or for people working in different sectors.

Conclusions

OSMs have the potential to increase the transparency, efficiency, and credibility of HE models, but several barriers hamper their widespread adoption, such as ensuring their updatability, legal concerns, and sharing confidential and person-identifiable data. Further efforts should focus on educating modelers in the technical aspects of OSMs, while ensuring that the HEOR community understands the opportunities and pitfalls of OSMs.

Supplemental Material

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.jval.2021.10.001.

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