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Decision-Analytic Modeling: Past, Present, and Future

Now Is the Time for Transparency in Value-Based Healthcare Decision Modeling

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ABSTRACT

In contrast to many other countries, during the 20 years since the founding of *Value in Health*, the United States has moved further away from using value-based healthcare decision modeling (VHDM) for drugs and other medical care choices. US public and private health plans can be typically characterized as using "budget impact" decision making rather than VHDM, with drugs having low per-member per-month spending likely to be covered and reimbursed regardless of value. Orphan drugs and specialty drugs with relatively few patients (eg, end-stage cancer drugs) are often covered, whether cost-effective or not, because health plans want to avoid negative publicity. Although there are many explanations for the poor US uptake of VHDM, a key reason is that VHDM models and data often lack transparency and are not generally made available to researchers for independent verification and reproducibility. This violates the scientific method, and is counter to the stated position of the National Academy of Sciences and the top journals in the sciences and social sciences. *Value in Health* and related peer-reviewed journals could make a key contribution to improving scientific rigor and real-world healthcare decision-maker acceptability by requiring that VHDM models, source code, and data used in published articles be made freely available to interested readers.

Keywords: economic models, open source, public use

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In an ideal world, there would be sacred tablets stored in the cloud (made of stone, Apple, or Android) that would tell us what each drug is worth for every possible patient and which treatment has the best value. In the real world, calculating these values can require complex economic models that may crucially hinge on often untestable assumptions about long-term treatment efficacy and safety, disease progression, utility and survival gains, treatment costs and cost offsets, and other key parameters. Lack of transparency in the economic models used to calculate drug value is a fundamental barrier to widespread adoption of a value-based drug pricing framework. Although not the only reason that value-based drug pricing has failed to achieve a level of acceptance in the United States comparable with other countries, encouraging scientific journal editors to require fully transparent and reader-accessible models, data, and programming code as a condition of model publication, subject to some reasonable limitations, would put our profession in line with other scientific fields and improve acceptance of our economic modeling methods, findings, and recommendations.

Before further exploring the advantages of greater transparency in value-based healthcare decision modeling (VHDM), let me first describe why boosting the acceptability of VHDM is so crucial, especially in the United States. When those of us on the International Society for Pharmacoeconomics and Outcomes Research's (ISPOR's) board of directors founded and named *Value in Health* 20 years ago, it was clear that promoting "value" in healthcare decision making was key to obtaining better healthcare resource allocation and improved health outcomes. With the Australian Pharmaceutical Benefits Scheme pioneering mandatory pharmaceutical cost-effectiveness evaluations in 1993, the Canadian Coordinating Office for Health Technology Assessment Economic Guidelines in 1994, and other countries, particularly the United Kingdom (with the National Institute for Health and Care Excellence founded in 1999), incorporating formal economic value assessments into national healthcare decision making and reimbursement policies, an international consensus on the importance of economic value assessment became firmly established during the 1990s.[1]

Even the United States, with the Public Health Service Task Force Panel on Cost-Effectiveness in Health and Medicine Report released in 1996, appeared to be getting on board.[2] But like the metric system, gun laws, and the rules of football, something unique to the American psyche and culture has prevented that which seems obvious elsewhere from fully taking root here. Going

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back to, at least, the failed 1990 to 1994 Oregon Medicaid Treatment Ranking Experiment, the 1995 closing of the Congressional Office of Technology Assessment, and the federal prohibitions on funding cost-effectiveness analysis in Medicare and the Patient-Centered Outcomes Research Institute, American politicians are wary about incorporating economic value-based assessment into healthcare decision making.[3–6] Federal law (eg, Medicare Part D) requiring coverage of certain drugs (eg, cancer drugs) in the United States is part of this failure to consider value. Moreover, the Affordable Care Act requirement that Patient-Centered Outcomes Research Institute explicitly not consider economic value has further pushed back progress on value-based pricing. No US public or private health plan directly promotes the economic value of their services, or openly discusses value in describing which drugs or medical interventions are covered or encouraged.

To the contrary, as seen in both the generic and branded market segments, the US drug market is deteriorating toward maximal price gouging, emboldening manufacturers to charge whatever the market will bear.[7] Although generic competition stimulated by the Hatch Waxman Act has lowered prices for most medications that Americans use, there have been increasingly frequent exceptions. A 2016 Government Accountability Office report found that 315 of 1441 generics had "at least one extraordinary price increase of 100 percent or more between first quarter 2010 and first quarter 2015."[8] Generics are not innovative and provide negligible amounts of pharmaceutical research and development. But in recent years, as the 450% EpiPen price increase epitomizes, they jack up prices enormously wherever they can get away with it.[7]

Similarly, branded drug manufacturers often ignore economic value in their pricing decisions, particularly for low-volume drugs. The incremental cost-per-quality-adjusted life-year (QALY) for many recently launched metastatic cancer drugs and other specialty drugs is far higher than meaningful societal or payer cost-effectiveness thresholds. For example, we found abiraterone and sipuleucel-T used in metastatic castration-resistant prostate cancer to have incremental cost-effectiveness ratios (ICERs) exceeding $400 000 per QALY.[9] Regorafenib and TAS-102 had ICERs of $804 001 and $627 443 versus best supportive care, respectively, in treating refractory metastatic colorectal cancer.[10] Ustekinumab had an ICER of $400 000 compared with etanercept in treating moderate to severe psoriasis therapy.[11] We also found an ICER of almost $700 000 in comparing reslizumab with standard of care in the treatment of poorly controlled eosinophilic asthma.[12]

In contrast to value-based pricing, the American drug market follows a "budget impact" pricing approach. Although US health plans care about drug safety and efficacy, they do not care much about whether a drug delivers value (eg, acceptable cost-per-QALY). They are very alert to what the drug's budgetary impact as measured by "per-member per-month" drug cost is to the health plan. A million-member health plan will not antagonize its high-cost orphan drug and specialty drug patients, because there are so few of them that each only adds a few dollars (or cents) to the per-member per-month health plan pharmacy budget, despite often outrageous per-patient costs and lack of economic value for many of these medications.

This budget impact pricing distorts not only comparative treatment values but also pipeline drug research and development. Drugs are now typically developed, designed, and priced to fly below the budget impact radar screens used to make coverage decisions. When a really valuable drug, such as sofosbuvir for hepatitis C, is introduced at a justifiably high price, health plans, pharmacy benefit managers, and politicians ignore whether the drug delivers good value; they care only about the budget-busting drug spend. Even at $1000 per pill, Harvoni (ledipasvir/sofosbuvir) can be cost-effective, because it cures hepatitis C in 12 weeks.[13] But because 3.5 million Americans suffer from hepatitis C instead of the 200 000 or fewer patients who could be treated by a typical orphan drug, US health plans have demonstrated that they care much more about total drug budgets than delivering good value for money.

Although value (cost-per-QALY) thresholds are not the complete solution to drug and healthcare cost issues, they can provide fair, efficient, and equitable healthcare decision guidance.[1] It is dispiriting to see the United States falling even further behind the rest of the world than 20 years ago when *Value in Health* was launched. Why have not we been able to convince providers, health plans, patients, and politicians that value pricing has value? After all, it is widely and persistently claimed that between 10% and 30% of US healthcare is unnecessary or actually harmful (ie, the low-value hanging fruit). An amount of 10% to 30% of $3.3 trillion in annual US healthcare spending is money that could solve critical problems facing the country.[14]

There are many explanations for the failure of VHDM in the United States: (1) the siloing of healthcare spending, particularly in Medicare Part D, so that pharmacies and pharmacy benefit managers are responsible only for the drug portion of medical care spending; (2) an American cultural myth that limits simply do not apply; (3) politicians who promise pie in the sky while attacking honest opponents offering painful choices; (4) powerful special interests, such as pharmaceutical manufacturers and their prescriber allies, who lose profits and influence when healthcare spending is rationalized; (5) technical difficulties in explaining concepts such as cost-per-QALY, or how complex VHDM models work; (6) difficulties in educating providers and health plans to use VHDM models effectively in real-world decision making; and (7) most VHDM models are proprietary black boxes, failing to follow fundamental scientific principles of transparency and independent reproducibility.

To keep this article manageable, I will focus on just VHDM model transparency and independent reproducibility. This is where science- and evidence-based organizations like the ISPOR and journals like *Value in Health* can have great immediate impact but where we have failed to push as far as our colleagues in many other disciplines of science and social science.[15] Although it is a debatable and ultimately empirical question as to whether greater VHDM model transparency and reproducibility will increase its acceptance and use by US healthcare providers and decision makers, there is no debate that for VHDM models to be characterized and accepted as more than mere opinion or advocacy but rather as following principles of scientific inquiry, they must be fully transparent and independently reproducible.

This was clear to the National Academy of Sciences in 2003 when it wrote[16]

> Principle 1. Authors should include in their publications the data, algorithms, or other information that is central or integral to the publication—that is, whatever is necessary to support the major claims of the paper and would enable one skilled in the art to verify or replicate the claims.

And further wrote, "Community standards for sharing publication-related data and materials should flow from the general principle that the fundamental purpose of publication of scientific information is to move science forward. More specifically, the act of publishing is a quid pro quo in which authors receive credit and acknowledgment in exchange for disclosure of their scientific findings. An author's obligation is not only to release data and materials to enable others to verify or replicate published findings (as journals already implicitly or explicitly require) but also to provide them in a form on which other scientists can build with further research."

Model builders and authors in all scientific fields increasingly face stark choices. They can either claim scientific rigor and standards in publishing their model results, in which case they can publish in the best and most prestigious scientific journals but with an obligation to share their data and models, or they can claim proprietary ownership of the intellectual property embedded in their undisclosed data and models, in which case their publications will be increasingly relegated to low-quality, low-impact factor journals or to nonscientific marketing and promotion materials.

Stodden et al[15] report a trend toward increasing editorial requirements for turning over these materials to interested readers. Moreover, higher impact journals were adopting open data and code-sharing requirements more readily than lower impact journals. The top 4 journals, *Nature*, *Cell*, *Science*, and *Nature Genetics* (all with impact factors >30), each require data sharing and/or code sharing with readers upon publication. Many journals now have similar statements to the author instructions of the Proceedings of the National Academy of Sciences (PNAS; impact factor 9.7), which states, "To allow others to replicate and build on work published in PNAS, authors must make materials, data, and associated protocols, including code and scripts, available to readers."[17]

The economics profession has also moved in this direction.[18] Many of the top economics journals have unambiguous policies on data and model sharing. The American Economic Association states, "It is the policy of the American Economic Association to publish papers only if the data used in the analysis are clearly and precisely documented and are readily available to any researcher for purposes of replication."[19] This policy has also been adopted by the *Quarterly Journal of Economics*.[20] The Econometric Society author instructions state, "Econometrica has the policy that all empirical, experimental and simulation results must be replicable. Therefore, authors of accepted papers must submit data sets, programs, and information on empirical analysis, experiments and simulations that are needed for replication and some limited sensitivity analysis."[21]

Medical journals have been much slower to adopt model and data transparency. *The Lancet* author instructions encourage but do not mandate transparency: "We encourage authors to share any additional data, preferably translated into English, that would facilitate the replication or further analysis of their work—e.g., the raw numbers underlying their analysis or the code for any modelling."[22] Other top medical journals (eg, *New England Journal of Medicine* and *JAMA*) have not yet mandated data-sharing policies. Although many scientists and clinicians advocate the sharing of all clinical trial data as a quid pro quo for publication, some argue there are unique issues of patient confidentiality and that clinical trial data sharing could deter medical innovation if would-be competitors could access confidential commercial information.[23] Nevertheless, these putative justifications would rarely even apply to economic models, which typically do not need confidential commercial or patient data.

Even beyond clinical trials, there are certainly research situations where some nuances in data- and model-sharing publication policies are necessary. These include data that might facilitate human subject privacy violations, terrorism, bioterrorism, national security breaches, or complex databases or models that have taken years of dedicated researcher time to develop (eg, the human genome or brain mapping projects, planetary mission data, or some artificial intelligence algorithms). Editorial oversight will always be needed to weigh the benefits and costs of data and model sharing against publication for these edge cases. Nevertheless, VHDM models and data seldom face such exceptional circumstances.

Thus far, VHDM journals and model builders have not followed the guidance of the National Academy of Sciences or the higher quality scientific journals. The Institute for Clinical and Economic Review, a primarily health plan–sponsored advocate for using VHDM models, does not itself even have any requirements for the peer-reviewed scientific publication of its supported "research." It also has explicitly rejected mandatory model and data transparency in favor of posting of a "… modeling analysis plan … intended to provide enough information for an experienced researcher to be able to replicate the economic model and analyses. Actual executable models and associated computer code will not be provided as part of the deliverable, as such an effort would unduly compromise the intellectual property rights of ICER's external collaborators."[24]

In contrast, the 2012 ISPOR-SMDM Modeling Good Research Practices Task Force report on model transparency and validation took the position that "… modelers should provide full technical documentation (along with access to a working copy) to readers designated either by a journal reviewing a paper or by an organization to which the model is provided for decision making, under agreements protecting intellectual property."[25] Although an improvement over the Institute for Clinical and Economic Review policy, this still does not go as far as the National Academy of Sciences recommends in terms of providing full model and data disclosure to all interested readers.

In 2017, *Medical Care* published a point-counterpoint commentary exchange on whether mandatory sharing of VHDM models and data should be a condition of publication in peer-reviewed journals.[26] Padula et al[27] took the position that there should be no requirements on disclosure of VHDM models and data because that could unfairly expose such models to unlicensed expropriation by competitors, and unscrupulous users could create alterations to warp or distort model findings and conclusions.[27] Cohen et al[28,29] expressed the counterpoint that requiring model and data sharing will not discourage publication of VHDM articles because this information is of limited proprietary value beyond the specific peer-reviewed article application and because the ability to gain additional citations in high-quality peer-reviewed journals through transparency makes up for such losses. Moreover, model and data sharing are more likely to deter unscrupulous users from distorting findings, because such distortions will not survive peer review scrutiny and/or correction in high-quality journals.

Additional arguments support open disclosure. No one forces a VHDM researcher to publish their results in the peer-reviewed scientific literature. If a researcher wants the prestige of doing science rather than advocacy, they should submit their peer-reviewed work to the rigors of the scientific method. If a researcher believes that their models or data are worth more as proprietary trade secrets, they can offer their work in private markets under whatever licensing agreements they choose. The right to publish an article in a high-quality journal should carry an obligation of transparency and cooperation with reviewers and readers who want to understand exactly how published results and conclusions are derived so that they can independently replicate and build on them.

As it is, most VHDM models and data contain little innovative intellectual property. Standard modeling techniques such as decision trees, Markov models, partitioned survival analyses, discrete event simulations, and agency modeling methods are widely understood by persons of ordinary skill in the art, as are software packages such as Excel, R, MATLAB, TreeAge, @Risk, Crystal Ball, and Arena. Most intellectual value added in building VHDM models relates to the specific parameters, variable ranges, and functional forms embodied in the model programming code itself. Although these are often incompletely and inadequately described in model write-ups and supplemental appendices, they

Table 1. Points supporting encouragement of journal editors to require fully transparent models.

Key points	Pro point	Con response	References
The scientific method means independent verification and reproducibility of findings	The scientific method is the criterion standard for generating rigorous evidence and advancing knowledge. It requires open and independently verifiable data, models, statements, findings, and assertions.	What is so great about science? Why not allow nonscientific methods also?	Stodden et al,[15] National Research Council,[16] National Academy of Sciences[17]
Model and data sharing increases acceptability and credibility of results	Economic models can be seen by key decision makers as proprietary black boxes designed to give biased results. They are thus fully discounted in most decisions.	Most decision makers do not understand these models anyway. Why give them information they cannot or will not use and may misuse?	Cohen,[28] Cohen and Wong[29]
Technical documentation is no substitute for data and model programming code	Although documentation is helpful, it is never the same thing as actual source code or data. Reverse-engineering models from documentation will always be approximate at best. If the documentation is so complete that the model can be reverse-engineered, why not just turn over the model anyway?	Good technical documentation may provide enough information to re-create a simple model and evaluate its results.	Institute for Clinical and Economic Review,[24] Eddy et al[25]
Requirements for full transparency in models and data for peer review publication are proliferating	Given that the National Academy of Sciences formalized this guidance 15 y ago, these standards are not proliferating fast enough.	Why do something just because it has become fashionable?	Stodden et al,[15] Ross and Krumholz[23]
Transparency makes models more accurate and reliable	Although not all models will be examined by everyone, some researchers will go through important models carefully and will alert others to any problems through publications, commentaries, and social media.	Public domain data, models, and software will be manipulated by nefarious special interests to distort the true findings or policy implications.	Cohen,[26] Padula et al,[27] Cohen et al[28]
Open publication expropriates intellectual property rights	Often the authors have invested a lot in model development and data analysis. Why should others be allowed to exploit that investment for free?	Economic models often have minimal proprietary value. If valuable, authors can sell their proprietary models or data under voluntary contracts. Nevertheless, once authors seek peer-reviewed publication of their results, scientific standards apply, including full transparency for independent reproducibility. Publication in a prestigious peer-reviewed journal is worth more than the ability to sell the model or data privately.	Padula et al[27]
Some models and data contain confidential information, huge upfront research investments, or trade secrets	Researchers will not invest in complex burdensome models or data collection if anyone can simply start using everything they created without compensation for these investments. Confidential information and trade secrets often must be protected by law or by legal contract.	Journal editors will establish standards to protect information in legitimate cases where enormous researcher investment, confidential information, or trade secrets might be expropriated or revealed. These are rare edge cases in the health economics field and can be handled on a case-by-case basis. If an author wants the prestige of a scientific publication, then they must live by the scientific rules of transparency and independent reproducibility. Redaction of confidential information is generally feasible.	Stodden et al,[15] Ross and Krumholz[23]

will always be clear and unambiguous in the model and sensitivity analysis programming code. In most circumstances it is hard to argue that things such as parameter values, ranges, or functional forms constitute proprietary intellectual property. These are exactly the items that readers and reviewers should be entitled to see and comprehend as they consider the results, robustness, strengths, and weaknesses of any particular VHDM model or data report.

Notwithstanding the Institute for Clinical and Economic Review's putative claims that their modeling analysis plans are sufficiently detailed to allow "experienced researchers" to replicate the economic model and analyses, it is wasteful and inefficient to force researchers interested in replicating VHDM models to glean incomplete and ambiguous information from model plans, references, and appendices rather than from the models, data, and source code directly. This unnecessary decoding, reverse-engineering, and model reconstruction chore discourages researchers from conducting the most important task in the scientific enterprise itself, namely, ensuring that scientific claims are testable and independently reproduceable.

As shown in Table 1, VHDM models and data openly shared with scientific journal readers and reviewers will engender more credibility and acceptance than proprietary black boxes asserting irreproducible claims on faith. Ironically, many, if not most, VHDM models and data are fully financially underwritten by sponsors such as pharmaceutical manufacturers, health plans, government agencies, or nonprofit organizations. It is not unusual for sponsors to pay 2 or more times for the same intellectual property in revised VHDM models and data that they paid to have developed in the first place. Although government agencies typically require full model and data transparency as a contractual clause, health plans, pharmaceutical manufacturers, and other private sector VHDM sponsors can improve the credibility and reliability of sponsored work while reducing unnecessary duplication of effort and cost if models and data associated with high-quality journal publications were increasingly made transparent. This transparency will enhance the influence VHDM models have on healthcare decision making, which will create a positive feedback loop: stakeholders will have incentives to validate/replicate models, which will further increase transparency.

Ideally, when a new metastatic cancer drug, cholesterol inhibitor, or hepatitis C drug becomes available, many VHDM practitioners in academia, industry, government, and nonprofit organizations would be able to quickly access existing public domain models and data to accurately and reliably project the relative value of the new treatment for various population subgroups. This would convert the current laborious secretive cottage industry of VHDM model building into a set of public domain Internet tools that could actually improve real-time value-based decision making for health plans, providers, and patients. The promise of achieving actual "value in health" decision making for real patients could finally achieve takeoff.

There are limitations and difficulties in moving toward VHDM open-source utopia. As mentioned, some types of modeling and data deserving of scientific publication may be too sensitive or represent too much of an upfront research investment to be immediately available in the public domain. Editorial oversight will be needed to handle such exceptions, probably quite rare in the VHDM research field. In some cases, time limitations for data sharing, anonymity requirements, or other narrow restrictions on what will be released into the public domain can be established as a condition of scientific publication.

There are legitimate concerns about burdens of VHDM publication authors in granting full open access to their models and data. Models of high complexity may be inadequately documented for all readers and may be difficult to follow. Just because a model is placed in the public domain does not obligate the model's author to fully annotate and explain each line of source code for any interested reader regardless of experience level. Model annotations, social media blogs, and posted comments will assist the research community in understanding and ranking model and data disclosures. Similarly, by sharing models and data in the public domain, model validation and replication will not depend solely on the discretion of journal editors and reviewers. As the ISPOR Consolidated Health Economic Evaluation Reporting Standards report stated, "There is evidence that the quality of reporting of economic evaluations varies widely and could potentially benefit from improved quality assurance mechanisms."[30]

It may be reasonable to impose a time window (eg, 5 years) after which obligations to maintain or support public domain models and software expire. It may also be reasonable for journal editors to allow publications based on large initial proprietary investments in modeling or data development to be granted an upfront blackout period (eg, 1-2 years) to allow them to generate several publications as a head start to the sharing of their valuable data and models in the public domain.

I am less concerned about the deliberate misuse of open-source VHDM models by self-interested parties to distort drug valuations than the unintentional misapplication of a model to generate incorrect results. But open-source models are inherently self-correcting. As in other scientific fields, VHDM researchers will improve understanding as well as gain additional publication credits through demonstrating errors or weaknesses in open-source models or data. Ultimately, as VHDM articles come to be seen as rigorous scientific research, rather than simply as special interest marketing, promotion, or advocacy, they will gain the reliability and acceptance that too often limit their credibility and use by healthcare decision makers today.

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