EDITORIAL

EPA's proposed transparency rule: Factors to consider, many; planets to live on, one

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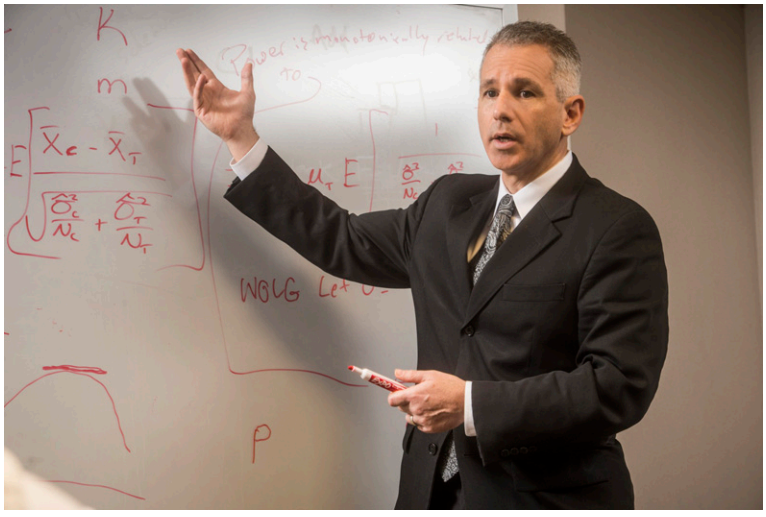
"In God we trust. All others bring data."
So reads a T-shirt sold by the American Statistical Association. This pithy quip encapsulates a fundamental principle of science: Scientists rely on evidence rather than authority. Indeed, "doubt has been considered essential to science since long before the scientific method was established in the 17th century" (1). Scientists seek reasons for why something should be believed as true, and those reasons involve data, the methods used to collect those data, and the logic connecting those data to conclusions. All other things being equal, absent the opportunity to fully inspect the data, methods, and logical connections of a study, scientists are less able to judge the validity of conclusions or the truth of propositions drawn from a study. As many of us heard from our middle school mathematics teachers, it is important to "show all your work." Generating and evaluating the scientific evidence to form conclusions about the truth of a proposition is fundamental to the work of science.

Notably, the Environmental Protection Agency (EPA) is not a scientist; it is a regulatory agency. EPA employs scientists and uses science to aid in its mission, but its primary mission is regulation and the protection of the environment and the public health, rather than simply drawing scientific conclusions. Regulatory decisions can, are, and should be informed by science. But science alone is not dispositive of regulatory decisions, and one should not conflate the role of scientists *qua* scientists with the role of scientists working in a regulatory process. Scientists working in a regulatory process must utilize the best information available to fulfill their charge of making decisions that benefit society, often under conditions of uncertainty.



David B. Allison. Image courtesy of the University of Alabama at Birmingham.

EPA proposed a rule in 2018 that would require any study pivotal to its regulations to make its data publicly available (2), and opened a period of public comment. The agency received nearly 600,000 comments (3), indicating the intensity with which many members of society attended to this proposed rule. Many comments, especially those from the academic and scientific communities, were highly critical of the proposed rule. The presidents of the National Academies issued a joint commentary on the proposed guidelines in which they opined that the proposed rule, at least with modifications, was neither good nor bad, but rather stated that clarifications regarding implementation were warranted and that poor outcomes could result if such clarifications were not included (4).

Given the central role of methods, data, and logic in science, who could argue with greater transparency? Indeed, as stated earlier, we are enjoined to "show our work." Legitimate concerns have been raised that some scientific work and conclusions may not be valid or reliable and that we can discern this only if data are transparent and reproducible. Notably, such concern about the rigor, reproducibility, replicability, and transparency of data and studies is not new. Indeed, even Galileo's famous experiments on pendulums led him to a conclusion we now know is valid for only a subset of circumstances. Yet Galileo claimed the conclusions were correct for a broader category of circumstances, leading some to suggest that he may not have actually done all of the experiments he claimed to have done (5) and others to note that his descriptions of experiments are

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not sufficient to permit confident replication. So, yes, reproducibility and transparency are good. Show us what you have done so we may judge its validity and so that we may try to replicate it if we so choose. And yet, an apt point to consider, when thinking about the environment and an agency charged with protecting it, is the ecologist's maxim, "We can never do merely one thing" (6). That is, when one does one thing, one always inadvertently does other things as well.

One might say, "What else would one do besides promote reproducibility, transparency, and, ultimately, better science by requiring that all data in studies used by EPA be reproducible and transparent?" Well, that depends on who is asked and who is trusted. Trust is the crux of the contentious points in question. EPA itself has long expressed a desire that its regulations both be and be seen as credible and based on sound science, stating, "Science enables us to identify the most important sources of risk to human health and the environment, and by so doing, informs our priority-setting [and] ensures credibility for our policies" (ref. 7, p. 26). Yet, even decades ago, expert panels expressed concerns about the extent that EPA is meeting and merits being seen to meet this credibility objective, with one stating, "Currently, EPA science is of uneven quality, and the Agency's policies and regulations are frequently perceived as lacking a strong scientific foundation" (ref. 7, p. 29). Such concerns remain palpable today, as voiced by journalists, scientists, and members of Congress.

Some would argue, not without justification, that, by making the data and methods upon which EPA bases its decisions publicly available, others could assess the validity of the research and the extent to which it supports the decisions made. This would arguably lead to reduced potential for others to manipulate data and studies and present their results in misleading ways, because such manipulation would become obvious, would lead to inadvertent errors being detected, and would lead to a greater understanding of the sensitivity and robustness of the results to analytic decisions. This, plausibly, would lead to greater trust in those data and studies that are ultimately incorporated into EPA's decision-making process and greater trust in EPA itself. That lofty purpose behind the transparency rule has been endorsed by members of Congress with statements such as that from Congressman Bill Posey (Florida): "In the past, EPA has relied upon secret studies to move forward with a particular political agenda. These studies were used to justify regulations that would have negatively affected thousands of people. For example, EPA sought to regulate fine particulate matter or airborne dirt. This would have particularly hurt the agriculture business, which is the second-largest industry in the State of Florida. There would be no way to test the data used to make the regulation because it was secret. I have a problem with that obviously, and I believe we should have transparency" (8). This viewpoint is one in which EPA seems to be effectively saying they agree with the American Statistical Association T-shirt: We don't want to trust any individual; if we put our trust in anything, we want it to be data, and we want to see those data.

Harvey V. Fineberg. Image courtesy of James Duncan Davidson/TED.

Yet, there are other perspectives about trust. Who will make the decision as to which studies merit exceptions to the rule? In the current publicly available EPA draft rule, this authority is relegated to one individual, the director of EPA. EPA directors are political appointees and not necessarily scientists. This leaves the decision-making authority in the hands of a single individual without the checks and balances of multiple perspectives, and an individual who may not have the scientific background to fully appreciate the data and study question. This leads many to the idea that EPA's proposed rule will erode trust in both EPA and, more fundamentally, EPA's decision process and decisions, by undermining the "warrant" to which expert consensus can contribute (9, 10). This view is typified by statements in Congress such as "The requirement for data to be publicly available is nothing more than an attempt to undercut EPA's mandate to use the best available science. I believe this is part of an effort to destroy regulations that protect public health but are opposed by some regulated industries" (11).

Reproducibility has been defined as "obtaining consistent results using the same input data, computational steps, methods, and code, and conditions of analysis. This definition is synonymous with 'computational reproducibility'" (ref. 12, p. 46). Importantly, reproducibility is neither a necessary nor a sufficient condition to ensure the validity of conclusions drawn from research. A study may be inherently flawed and inappropriate for supporting a conclusion and yet may be fully reproducible by the definition above. In contrast, studies may be irreproducible for many reasons which do not necessarily mean that the conclusions drawn from those studies are invalid. As noted in a National Academies report, "Certainly, reproducibility and replicability play an important role in achieving rigor and transparency, and for some lines of scientific inquiry, replication is one way to gain confidence in scientific knowledge. For other lines of inquiry, however, direct replications may be

impossible due to the characteristics of the phenomena being studied. The robustness of science is less well represented by the replications between two individual studies [or reproduction of one or more studies] than by a more holistic web of knowledge reinforced through multiple lines of examination and inquiry" (ref. 12, p. 143).

Given this, many studies which might be uniquely informative and offer sound scientific evidence on which to base policy decisions might be excluded from the process. Again, this might be fine for a scientist *qua* scientist drawing conclusions about the truth of a proposition who might justifiably state that he or she is unwilling to declare a proposition to be demonstrated unless some rigorous standard of science has been met, but it is not appropriate for a decision-making entity which has the goal of making prudent decisions. Such a decision-making entity should base its decisions on the best available information (13), even when that best available information may not support definitive scientific conclusions (14).

Alternatively, supporters of an absolute requirement that data and studies may be included in the decision-making process only if they are reproducible and transparent might argue that, because all studies can be made reproducible and transparent, scientists should simply do so and there will be no dispute. Unfortunately, the premise for this argument is false. Not all studies can be made reproducible and transparent, even by careful and well-intentioned scientists. This is so for multiple reasons. Perhaps the most obvious—and a frequent topic of public commentary and congressional testimony—are privacy and contractual concerns regarding human subjects' data. Many have indicated that, in some studies, participants are promised that their data will not be shared with anyone beyond the immediate investigative team, or that disclosure of the data would potentially disclose the identity of the individual. Both concerns are legitimate, as eloquently described by Marie Lynn Miranda (15) and as passionately argued for in the testimonies of Drs. Linda S. Birnbaum and Mary B. Rice (8). One might counterargue that methods are available to allow such data to be used while protecting participant privacy. Indeed, many such methods are potentially available. Yet no method is foolproof. Time and again, clever statisticians and bioinformaticians have shown that, given enough data, they can often identify individuals in datasets even when the dataset presumably masked the identifies of individuals (16). Even beyond that, there are questions about costs. Datasets can be "perturbed" to add random error in a way that masks identities, or analyzed in secure locations rather than making them fully public. These are valuable and viable solutions, yet, in some cases, implementation adds delay and expense. Will such expense in terms of both time and money always be warranted? Will such expense always be affordable? In cases where the answers are no, this, again, may unnecessarily limit the inclusion of valuable scientific information.

The extensive narrative and discussion around protection of privacy or the honoring of implicit or explicit contractual obligations with research subjects is an important one, but it would be misleading to think that these are the only impediments to reproducibility and transparency of data in studies and, therefore, that overcoming them would counter any arguments against EPA's proposed rule. Notably, some older studies may not be able to be made fully reproducible and transparent, because of inadvertent data loss as the result of honest error or changing standards for data storage and maintenance. This is especially apt in important longitudinal studies, which may have been ongoing for decades, and for which data may not be available because of the effort or time required to obtain data or knowledge of requisite ancillary metadata that are forgotten or died with the original investigator (17). Hence, even some valid data that do not involve human subjects, such as on model organisms or on environmental readings, may not always be reproducible and transparent.

Importantly, confidence in results can be obtained in other ways. These include peer review, replication [defined as "obtaining consistent results across studies aimed at answering the same scientific question, each of which has obtained its own data" (ref. 16, p. 46)], demonstration of generalizability, and yet other procedures (13, 14, 18, 19).

Another issue concerns the opportunity for reanalysis of extant studies to introduce bias. Legitimate concerns exist that original research may not only contain inadvertent errors but have used biasing procedures. Original analysts may have "p-hacked" (20, 21), used undue "researcher degrees of freedom" (22), or followed the "garden of forking paths" (http://www.stat.columbia.edu/~gelman/research/unpublished/p_hacking.pdf) to produce a result desired by the original analysts. Yet, those very same concerns can be raised about reanalyses that would be conducted by EPA, unless EPA were to commit to publicly preregistering their analytic plans in advance of obtaining the data, and their current proposed rule specifies no such plan.

So let us return to trust. Should EPA trust all reported conclusions from scientific papers without probing further and, where reasonable, requiring that the data and studies be made reproducible and transparent? In our opinion, no. This would not be a sound way to rely on scientific information in informing a decision-making process. EPA is wise to take steps to make the science they rely on reproducible and publicly available when feasible. In doing so, EPA will be providing a service to and participating in promoting greater openness and rigor within the scientific community at large. But should EPA bind itself to consider scientific evidence only for which the underlying data are reproducible and publicly available or for which an exception is granted by a single individual? Again, in our opinion, the answer is no. Doing so would replace EPA's legal and eminently reasonable mandate to make decisions on the "best available science" (13) with a self-imposed mandate to consider only reproducible and transparent scientific evidence. As we have argued here and elsewhere, reproducibility and public availability of data, while valuable, are neither necessary nor sufficient markers

of the soundness of science and are not the only indicators of the soundness of science. Therefore, relying only on reproducible studies and publicly available data cannot be taken as equivalent to using the best available science, and adopting such a restrictive policy would be contrary to EPA's responsibility.

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