Of Research Cycles and Publication Models

Kirstie M. McClure

This response to Prof. Lieberman's essay questions its analogy between "biomedical research" and the academic discipline of political science. Focused on the disanalogy of scope and scale between the two, it takes issue not with the "criterial framework" he offers, but with the quality of argumentation that leads us there. Supplementing the essay's impressionistic account of editorial practice with evidence drawn from the New England Journal of Medicine and the publishing history of APSA journals since the 1960s, I suggest that the issue here is not simply editorial virtue and professional norms, but differences in the material and institutional bases of the journals' alternative publication models.

Positing "the biomedical research cycle" as a model for political science, Evan Lieberman juxtaposes editorial care in biomedical journals for the progressive, step-wise phases of that cycle[1] against the relative absence of such concern in leading political science journals. Distinctive here is his operational "notion" of such a cycle as a communicative practice "constituted as a scholarly conversation through peer-reviewed publications" (ms. p.2). Mixing "inductive and deductive theorizing and observation," this conversation "explicitly recognizes differences in the state of research within a substantively delimited cycle" and anticipates movement from "more tentative to more definitive claims about causal relationships." Notably, this is not about diversifying research topics or methods; at stake here is the discipline itself as an honest and cumulative scientific enterprise. By overemphasizing rigorous causal analysis, Lieberman argues, our disciplinary norms both encourage exaggerated causal claims and devalue more exploratory observational and descriptive studies. Absent publication of work at the upstream end of the process, the editorial practice of our leading journals thus entails significant costs: the (near) disappearance of any extended research cycle from public view, the discouragement of discovery, and the professional deformation of rising scholarly cohorts over time—all to the detriment of the discipline's scientific promise.

Hence the punch of Lieberman's sharp contrast between political science journals and the research cycle he sees in the *New England Journal of Medicine* (NEJM hereafter). While the NEJM editors appear "well aware that progress" on difficult substantive questions "requires movement through a research cycle" (ms. p.1), the more myopic practice of political science invites reformation of our norms and practices of professional judgment. Accordingly, after setting out "the biomedical research cycle," the later sections of the essay address the practical tasks of developing a framework for a political science research cycle, elaborating distinct criteria appropriate to each of its stages, and marking the relative value of pre-analysis plans across those stages. The upshot of that exercise, Lieberman's "Criterial Framework for Assessing Contributions in a Political Science Research Cycle," strikes me as a handy resource for editors, reviewers, and researchers alike.

Paradoxically, while appreciating the utility of that framework I'm unpersuaded by the argument that gets us there. In what follows I raise some concerns on the distaff side of the analogy between biomedical research and political science. My aim in doing so is not to refuse but to complicate and supplement Prof. Lieberman's original provocation, by considering whether there are relevant disanalogies undergirding the differences he senses between the two publication models.

For instance, consider the pivot of the argument from the perspective of scale. Lieberman's "research cycle" is a conceptual hinge for contrasting the public/published face of a loosely-coupled academic discipline against that of a highly-regulated, complexly-organized, industrial-scale, multidisciplinary research enterprise. Activities

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included in the latter range from a number of basic sciences and advanced technosciences, through clinical trials, to clinical practice and therapeutic improvements in patient health, to public health initiatives and assessments of their impact. Lieberman's essay, however, makes a conceptual slide that abruptly narrows that complexity. Rhetorical invocations of "biomedical research" have pride of place throughout—but the publication selected to exemplify biomedical editorial practice is a journal of "clinical medicine" (ms. p.5). Appearing only once, that phrase specifies the research cycle at issue here as the phased experimental practice of clinical trials—a move that effectively abridges the range of "biomedical research" to one of its parts. Less grand but more accurate, perhaps a better title for the essay might be "Can the Clinical Research Cycle be a Model for Political Science?"

Or would that be too hasty? If only a part, clinical research is a centrally located part of the dynamic and heterogeneous complex of institutions, disciplines, and practices of what some call the "biomedical research continuum" of our post-genomic times.[2] Owing in part to the accelerated pace of basic research and associated technosciences, and in part to the expanding landscape of public health, a major concern today is how to "translate" the diverse forms of knowledge produced at different locations in the process into improved health outcomes for both patients and populations. To simplify, dilemmas of "translational science" emerge at different moments of the continuum: at the juncture of basic science and clinical research, at passages of clinical trial results into clinical practice, and at end points of integration into the health care system with the delivery of improved health at the level of populations. In light of these perplexities, rather than narrowing Lieberman's provocation let's accept the claim that NEJM editors duly represent the clinical research cycle, then ask how they fare on the broader reaches of "biomedical research." Do they *also* attune their readers to the work of translation from laboratory to clinical research, and from clinical research to advances in patient care and public health?

Revisiting the NEJM issue Prof. Lieberman selected, by his litmus of editorial care the case here appears similarly strong. The "phase 1" and "phase 2" clinical trials he notes, for instance, both involve "bench to bed" translations of high-tech discoveries at the molecular level into clinical trials, while a "Brief Report" on a type of thyroid cancer uses next-generation DNA sequencing to identify a candidate-susceptibility gene in a single family. A fleeting glimpse of public health translation, on the other hand, arrives in the epidemiological study of pneumonia, for in its description of the incidence of the disease is a speculation that one of its findings (relatively low rates of bacterial pathogens) may be an indirect effect of childhood vaccination programs in the United States.

Yet beyond the material Lieberman selected, other articles in the issue also evidence translational dimensions in both directions. A "Perspectives" article, for example, touts that "phase 1" study as a structural approach to cancer drug development. There, two leading oncologists highlight the molecular science driving this research and assess the significance of its results. Two further "Perspectives" pieces mark translation dilemmas in the direction of public health. One takes the occasion of an HIV outbreak in rural Indiana to remark on shortcomings in the state's public health prevention strategies and substance-use treatment programs. The other reflects fifty years later on the Older Americans Act of 1965, considering its successes and challenges in relation to value-based care and community-based initiatives for elderly populations. Finally, a "Review" article on Chaga's Disease reports the current state of knowledge on the epidemiology, diagnostics, and treatment of this tropical disease, as well as its challenge to public health efforts in various parts of the Americas and elsewhere.

On Prof. Lieberman's view of editorial virtue, *NEMJ* thus does well with regard to both the clinical research cycle and the biomedical research continuum. How do they do it? Are they simply well-attuned to the relevant research norms, or might there be institutional dimensions to their success as well?

As my brief on translational aspects of Prof. Lieberman's issue suggests, NEJM differentiates its articles into kinds. Lieberman notes clinical trials from the "Original Articles" section, plucks the "strawberry tongue" from the "Clinical Images" section, and makes a passing reference to a 2006 "Perspectives" article to shoehorn "normative theory" into his empirical research cycle,[3] but he leaves the journal's format and other content unremarked. To go beyond a one-shot impression, I searched NEJM editors' "Editorials," from a 1991 editorial transition to 2016, for public accounts of what they were doing,[4] then perused the changing features of the journal that the editors mentioned. The paper trail there suggests a long-standing record of editorial responsibility to both the medical profession and the public, as well as an ongoing commitment to innovation in response to the rise of electronic communications and to the revolutions in the biomedical sciences up to and beyond the sequencing of the Human Genome.

For example, while NEJM's traditional emphasis on scientific research, clinical practice, and health policy was maintained, its format evolved considerably. Five new features arrived by the mid-1990s, three pertinent to translational issues of a "biomedical research continuum" from basic science to public health: "Molecular Medicine," "Clinical Implications of Basic Research," and "Health Policy Report," a long-running series on the American health care system.[5] Other article types include "Special Articles" and "Special Reports," devoted to timely and

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topical matters of scientific, clinical, or public health concern. The category "Perspectives," added in 2002, provides readers with specialists' more concise views of matters of similar importance, explaining complex scientific or public health developments in accessible language and often focused on an "Original Article" in the issue.[6] With features extending across the clinically relevant range of the biomedical research continuum, it's not for nothing that the NEMJ is widely regarded as an exemplary "general medical journal."

Given NEJM's scope, its editorial virtue is highly organized and, as its weekly circulation suggests, on a scale well beyond an academic discipline's quarterly. Its website reports 500,000+ weekly readers—as well as 5,000+ annual submissions, with 5 percent published and 60 percent desk-rejected. While "Original Articles" arrive over the transom, the editors solicit many other article-types (and encourage pre-submission inquiries for some). Its present Editor-in-Chief has a task- and specialty-differentiated editorial team of twenty-three, a fourteen-member Editorial Board, plus five statistical consultants and a sizeable technical staff.[7] No wonder NEJM has been able to respond to changes in its increasingly biomedical and technoscientific environment to keep its readers—always imagined as practicing physicians, clinicians, and public health professionals, as well as scientific researchers—communicatively well informed.

These two aspects of the NEJM, its crafted format and the scale of its editorial organization, may go far in accounting for the broad scholarly and professional conversation in its pages, both for the clinical research cycle and for clinically-relevant aspects of the biomedical research continuum.[8] Clearly, it has enjoyed an exceptionally talented and long-serving series of editors-in-chief, as well as executive, deputy, and associate editors devoted to maintaining its reputation—and, it would seem, to keeping its publication model spry enough to innovate constructively amidst tectonic shifts in both science and publishing.

Comparatively speaking, the late twentieth- and early twenty-first-century history of the *APSR*—the sole polisci journal Prof. Lieberman mentions—has left it differently conceptualized, organized, and institutionalized. Most notably, its changes have come less from ongoing editorial crafting and internal differentiation than from official subtraction, as APSA redistributed content across new journals. In 1968, professional communications, news, and correspondence were separated out to *PS,* leaving more room in *APSR* for research articles and book reviews.[9] In 2002 the book reviews went to *Perspectives on Politics*—itself envisioned as broadly responsive to timely and topical issues of the day, both political and professional—again making space in *APSR* for more research articles. Since 2001 *APSR* added editorial introductions for each issue, but it also ceased publishing shorter "Research Notes." The editorially-crafted Centennial Issue of 2006 aside, *APSR* content is now all research articles in a string, though occasionally enlivened by a "Forum" initiated by a scholarly critique of a previously published article. In short, the gradually evolving division of labor between APSA journals has left the *APSR* an undifferentiated, empty space for the free play of professional norms that Prof. Lieberman calls to our attention.

Call me a cynic, but I'm doubtful that exhortations to scientists' better angels, even with criterial frameworks taped to their harps, are likely to go far by themselves. Still, two interesting material opportunities have now appeared. First, in September the *APSR* went to a new editorial team, one that promised new presentation formats for different approaches to research.[10] Whether this might cohere or not with Prof. Lieberman's notion of "a" political science research cycle is a question worth raising—with him, with them, with ourselves. Second, in another significant response to the larger publishing environment, APSA's online-only open access journal may also roll out soon. There too, the question of possible implications for "a" political science research cycle might loom large—as chair of the search committee for the journal's editor/s, Prof. Lieberman might share some thoughts on that as well.[11]

Notes

1 That is, the cycle from "pure description, through correlational analyses and natural experiments, to phased randomized control trials"; (Lieberman, 2016, 1054).

2 See, for instance, Drolet and. Lorenzi 2011. As is often the case in areas of rapid change, the "continuum" these authors suggested in 2011 can take on other descriptors. NIH's National Center for Advancing Translational Sciences, for example, now speaks of the translational science *spectrum*. See https://ncats.nih.gov/translation/spectrum for details.

3 Colgrove 2006a. Derived from the lumpishly reductive APSA category of "Normative Theory," the temptation to classify this simply as the work of an "ethicist" misrecognizes the sort of political advice it provides. According to the author's website at Columbia's Sociomedical Sciences section of their School of Public Health, his research "examines the relationship between individual rights and the collective well-being and the social, political, and legal processes through which public health policies have been mediated in American history"; https://www.mailman.columbia.edu/people/our-faculty/jc988 For a sense of why Colgrove would be an appropriate expert to advise NEJM readers on the "ethics and politics" of compulsory vaccination, see his *State of Immunity: The Politics of Vaccination in Twentieth-Century America;* Colgrove 2006b.

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4 I draw here on two editors serving between 1991 and the present, Jerome P. Kassirer (1991–1999) and Jeffrey M. Drazen (2000–current). For the former see Kassirer 1991, 1992a and b, 1996, 1999 a, b, and c; and Kassirer and Angell 1995, 1997. For the latter see Drazen 2000 and 2005.

5 Kassirer 1996, 50. The other two were "Clinical-Problem-Solving" and "Images in Clinical Medicine."

6 Further categories include "Clinical Practice," sequentially numbered "Case Reports" solicited from the Massachusetts General Hospital, and "Sounding Board" opinion pieces, among others. The online edition hosts drop-down menus for Selected Specialties (cardiology, genetics, nephrology, etc.) and Featured Topics (Global Health, Medicine and Society, among others), all thematic collections of past articles indexed by subject. The online version now also features videos, images, and multi-media presentations as well as a time-delimited "Comments" function linked to recent articles of all sorts, a web-based Continuing Medical Education feature, and a sidebar link to medical employment opportunities.

7 See the masthead at http://www.nejm.org/page/about-nejm/editors-and-publishers.

8 This may also be the case for the other three journals that Prof. Lieberman identifies—the *Journal of the American Medical Association*, the *British Medical Journal,* and *The Lancet*—only the last of which is independent of a professional medical association. There are further institutional connections, too, relevant to his concerns about the distribution of article-types, exaggerated causal claims, and pre-analysis plans. These four journals numbered among the founding members of the International Committee of Medical Journal Editors in the late 1970s and their editors continue to serve in place. ICMJE began as an international effort to standardize the format of medical journal submissions. Its provenance soon expanded to standardizing conflict-of-interest reporting and now includes support for trial registry and pre-analysis plans as means for ensuring public confidence in 'evidence-based' medical and public health research. Over 2,700 journals now subscribe to its recommendations (see http://www.icmje.org/journals-following-the-icmje-recommendations/). For a brief history of ICMJE see Huth and Case 2004. The dilemma of causal over-claiming afflicts biomedical research as well. As *Lancet* editor Richard Horton (2015, 1380) recently observed, "Our love of 'significance' pollutes the literature with many a statistical fairy-tale."

9 Having become a venue for symposia and numerous other features of political and scholarly interest, PS evolved into *PS: Political Science and Politics* in 1988. Its new editorial team has introduced productive new features in the journal's content, most recently "News from the Sections." See their 2015 report at http://www.apsanet.org/Portals/54/files/Publications/Journal%20Files/Editor%20Reports/PS%20Editors%20Report_2015.pdf. Since its inauguration in 2002 *Perspectives on Politics*, too, continues to be a site for astute editorial crafting.

10 See http://www.apsanet.org/apsreditors.

11 See http://www.politicalsciencenow.com/call-for-proposals-apsas-open-access-journal/.

References

Colgrove, James. 2006a. "Ethics and Politics of Compulsory HPV Vaccination." *NEJM*, December 7, 355(23): 2389–91.

———. 2006b *State of Immunity: The Politics of Vaccination in Twentieth-Century America*. Berkeley: University of California Press.

Drazen, Jeffrey M. 2000. "Looking Forward to Serving You Every Week." *NEJM*, July 6, 343: 57–58.

———. 2015. "Fifteen Years." *NEJM*, October 9, 373.

Drolet, Brian C. and Nancy M. Lorenzi. 2001. "Translational Research: Understanding the Continuum from Bench to Bedside." *Translational Research* 157(1): 1–5.

Horton, Richard. 2015. "Offline: What is medicine's 5 Sigma?" *The Lancet, Vol. 385* (April 11): 1380.

Huth, Edward J. and Kathleen Case. 2004 "The URM: Twenty-Five Years Old." *Science Editor* 24(1): 17–21.

Kassirer, Jerome P. 1991. "The Relman Years at the *Journal*." *NEJM*, July 4, 325: 58–60.

———. 1992a. "Journals in Bits and Bytes." *NEJM*, January 16, 326: 195–97.

———. 1992b. "A New Book Review Editor." *NEJM*, May 21, 325.

———. 1996. "The *Journal's* New Look." *NEJM*, July 4, 335: 50–51.

———. 1999a. "Should Medical Journals Try to Influence Political Debates?" *NEJM*, February 11, 340: 466–67.

———. 1999b. "Editorial Independence." *NEJM*, May 27, 340: 671–72.

———. 1999c. "Goodbye, for Now." *NEJM*, August 26, 341: 686–67.

Kassirer, Jerome P. and M. Angell. 1995. "The Internet and the Journal." *NEJM*, June 22, 332: 1710–10.

———. 1997. "Controversial *Journal* Editorials." *NEJM*, November 13, 337: 1460–61.

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