EDITORIAL

Perspectives on the American College of Lifestyle Medicine's Strategy to "End the Tyranny of the RCT"

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I LEARNED VIA follow-up to an American College of Lifestyle Medicine (ACLM) webinar^{1,2} that the organization devoted to advancing multimodal lifestyle approaches to chronic conditions had a team at work developing a method to combat the damage from what their project leader has since called the “tyranny of the RCT” (randomized controlled

trial).³ I invited the ACLM leaders to provide a submission to *JACM*'s since-published Special Issue on *Multimodal Approaches in Integrative Health: Whole Persons, Whole Practices, Whole Systems*.⁴ The ACLM team contributed a piece on the misfit of the RCT with lifestyle medicine intervention in which they announced their internal collaboration to create a “Hierarchies of Evidence Applied to Lifestyle Medicine (HEALM).”

The ACLM's project and recommended directions via HEALM were recently published in *BMC Medical Methodology*.⁵ Their work, led by Yale preventive medicine, integrative medicine, and lifestyle medicine leader David Katz, MD, MPH, thus became part of the pattern of research insurgencies urging new whole systems research (WSR) models such as the one that Nadine Ijaz et al. examined in their review in the *JACM* special issue.⁶ The goal is nothing less than to elevate methods that respect the health-focused, preventively oriented, whole-person, tailored approaches such as are practiced in clinical lifestyle medicine that have, to date, effectively been suppressed by the pharmaceutically aligned disease management methods that flourish under reductivity's stern whip. Remarkably, Katz and his team choose strategically—as is shared below—to not reference the WSR opus anywhere. Katz portrays this decision as a tactical effort in a sort of game of thrones aimed at creating shared space at the top of the research pyramid.

The work is important—in both substance and strategy. The ACLM team includes some of the top researchers associated with the U.S. Center for Disease Control and Prevention (CDC). It pulses with gravitas. Notably, lifestyle issues and related interventions as promoted by the ACLM are constants across a broad band of traditional, Asian, naturopathic, and integrative clinical models. I contacted key WSR researchers associated with the *JACM* special issue for their perspectives on HEALM. Then, I reached Katz to learn more about the team's strategy. With the remainder of this editorial, I report what I found, in the words of these experts.

Nadine Ijaz, PhD

In her concise comment, University of Toronto-based researcher and certified herbalist Nadine Ijaz, PhD, the lead author on the recent *JACM* WSR review, references two of the integrative medicine field's most prominent WSR frameworks that predated the HEALM work.

The HEALM tool represents a valuable addition to the literature on evidence evaluation—and is likely to support dissemination of quality research that focuses on prevention and health promotion rather than sickness care alone. The tool actively contributes to (and participates in) a methodological paradigm shift that centralizes more holistic, integrative approaches in health care. The authors' critiques of the classical RCT's limitations with respect to behavioral interventions strongly echo those of whole systems research pioneers. Their tangible strategy for diversifying what ‘counts’ as legitimate clinical evidence recalls the ‘evidence house’ (Jonas)⁷ and ‘circular model’ (Walach et al.)⁸ proposals of researchers in the [Traditional Complementary and Integrative Medicine] field—and should be welcomed as such. That said, significant work remains to establish evidentiary tools that contextualize ‘lifestyle’ (and other) interventions more deeply within the social, structural and ecological determinants of health. (Nadine Ijaz, personal communication via email, August 2019)

Clinician-researcher Dugald Seely, ND, from the Ottawa Cancer Center and the Canadian College of Naturopathic Medicine—and a member of the *JACM* special issue

team—begins with a comment on the ACLM's tactical choice to start the paper with a review of existing strength of evidence (SOE) tools.

Dugald Seely, ND

This paper is important in two ways. First, it has collected and synthesized the evidence related to existing Strength of Evidence (SOE) tools. Second and more importantly, this work presents a new tool, the Hierarchies of Evidence Applied to Lifestyle Medicine (HEALM), as a means of combining and evaluating evidence on lifestyle-based interventions that includes longevity as an outcome. The HEALM tool is a much needed and exciting development. Limitations to most SOE tools includes an over-reliance on the RCT as the final arbiter on causality and value for healthcare interventions. David Katz and colleagues have used a process of mapping and scoring that combines research from mechanistic basic science, observational studies for generalizability plus scale, and controlled clinical trials to assess for causality and reduction of risks of bias. The primacy of the RCT is respected in this tool, however it also allows for the inclusion and framing of the evidence through other available sources of evidence. Through this, different types of research can be holistically combined to understand the totality of evidence available and assign a score (Grades A, B or C) associated with a degree of likely certainty of effect. The HEALM tool needs to be put to the test in assessing relevant evidence, but the tool presented is meeting a gap in healthcare research evaluation head on by allowing for and indeed welcoming the plurality of evidence available. (Dugald Seely, personal communication via email, August 2019)

Particularly notable for the purposes of this discussion is the reference to the SOE review. The HEALM team did not choose to begin its argument with the *prima facie* evidence that lifestyle medicine represents a practice paradigm that does not fit the reductive model. Nor do they begin by reiterating characteristics that define the whole systems practice paradigm—though most are congruent with the lifestyle medicine clinical model (e.g., multimodality, health-focused, individualized, mind-and-body). The team that referenced none of the WSR opus also chose to keep at arm's length any consonance with the WSR. Instead, as Seely notes, the ACLM team first report the results of a systematic scoping review that sets context from within the framework of the SOE dialogue. Then, they rest the case for their differences on a separate trio of concerns relative to evaluating lifestyle medicine interventions on which the SOE review came up nearly empty:

- Criteria to evaluate exposure-outcome relationships examined over years/decades/lifetimes
- Criteria to evaluate behaviors/exposures used in lifestyle medicine that may not allow for randomization or blinding (e.g., smoking, long-term dietary patterns, etc.)
- Guidance to synthesize findings from diverse study designs, except to prioritize RCTs over observational studies.⁵

One witnesses the bowing to the RCT, yet also the emergence of a model that, remarkably, evokes the broader culture context in which this medical-cultural power-struggle is engaged: diversity, on the one hand, and dominance of one perspective on the other. The HEALM team recommends a “systematically weighted approach” in-

volving multiple research models that “(increase) the weight and thereby validity of evidence specially applied to lifestyle interventions.” Seely celebrates HEALM's elevation of a more holistic and inclusive view of evidence.

Scott Mist, PhD, MSAOM, LAc

Oregon Health Sciences University Assistant Professor, acupuncturist and *JACM* statistics editor Scott Mist, PhD, MSAOM, LAc weighed in on ACLM's SOE work with a few brief comments that challenge the RCTs primacy.

One of the things that I have been interested in for a while is re-assessing the hierarchy of evidence. There has been a number of really good studies^{9,10} showing that large case studies—observational type research—correctly predict the outcomes of randomized clinical studies.

A counterpoint argument to these papers came from the editor of *BMJ*¹¹—but I thought that it was a weak argument—mainly saying that there are few good observational studies. There are caveats about the size, just like any other type of study, but I think that the field should be rethinking the role of observational studies and the primacy of RCTs. (Scott Mist, personal communication via email, August 2019)

Mist underscores the importance of looking beyond the RCT in suggesting methods that may make it share the throne.

Jennifer Rioux, PhD, AD, C-IAYT, AYT, RH (AHG), CCA-III

The second author with Ijaz on the WSR review is Ayurvedic practitioner and WSR researcher Jennifer Rioux, PhD. In a short essay included next in full, Rioux—who also offered original research and commentary for that issue—celebrates HEALM while challenging its limits. In particular, she questions its obeisance to an era in medicine, and medical research, dominated by the RCT. She challenges the HEALM team pointedly: “We may ask ourselves if the hierarchy-of-evidence-project plays a role in replicating colonial structures that serve to *prove* the supremacy of biomedicine and its attendant research methods, rather than to *improve* patient care overall.”

Developing innovative frameworks to evaluate evidence in studies of ‘lifetime cumulative effects of specific health behaviors’ is critical work. The HEALM tool highlights the suitability of research design for the question and supports a balance between evidence quantity and quality in varying combinations. The authors contend that it is useful to hybridize and tailor the evidence hierarchy to the specifics of lifestyle medicine, however their assertions repeatedly reify the supremacy of the RCT, while downgrading forms of evidence that are often more appropriate for studying traditional, complementary and integrative medicine (TCIM), as well as lifestyle medicine.

The term ‘hierarchies of evidence’ is problematic in holistic medical paradigms where understanding diagnosis and treatment may rely on arranging evidence *laterally*, allowing a primacy of evidence types to emerge as dependent on population, condition, nature of treatment, and outcomes of concern. There is increased understanding in lifestyle medicine that individualizing treatment and shifting treatment priorities over time are correlated with better outcomes. The shifting and emergent nature of evidentiary balance deserves attention, alongside hybridizing and tailoring the hierarchy.

I applaud the encouragement of diversified evidence sources and ‘an amalgamation of complementary evidence.’ However, the rating schemes they discuss continue to rely on privileging not just RCTs, but statistical measures like *p*-values for establishing ‘certainty about treatment effects,’ when it is widely understood that these can be manipulated in the direction of significance. We may ask ourselves if the hierarchy-of-evidence-project plays a role in replicating colonial structures that serve to *prove* the supremacy of biomedicine and its attendant research methods, rather than to *improve* patient care overall. This approach excludes evidential constructs that can be more democratically applied across medical paradigms, thus inhibiting interprofessional dialogue within lifestyle medicine.

The authors invoke non-RCT evidence as providing context for understanding causality while simultaneously acknowledging ethical and practical limitations of RCTs in lifestyle medicine. They state that *even* ethnographic studies can contribute evidence, then swiftly change tack, reminding us ‘but these are subject to bias.’ They focus on clarifying causal effects but do not acknowledge the specific, irreplaceable ways that qualitative research illuminates context and process, thereby facilitating a meaningful, patient-centered understanding of causality. Where is the patient’s voice in the hierarchy?

Discussion of the vast resources necessary to amass ‘higher’ levels of evidence is absent. Scale and complexity of TCIM research, in concert with lifestyle medicine, are naturally disadvantaged through resource deficiency. Limited resources necessitate a greater emphasis on observational studies and small-scale, no control, pre-/post-measures, leading to potentially higher risk of bias (ROB) (conventionally understood). An incurious discussion of RCT primacy replicates a research infrastructure that perpetuates consolidation of resources in the biomedical research community. Weighting and synthesizing evidence is valuable and would be enhanced by further unpacking a continued reliance on quantitative hierarchies, RCT supremacy, and unexamined ROB conventions. Without a rigorous exploration of these foundational assumptions, the HEALM tool replicates the social and political order of privilege in research communities. (Jennifer Rioux, personal communication, September 2019)

It is clear from points made earlier that Rioux’s argument does not end with the imbalance in power struggles between research communities. Rather she turns attention to the ways that she believes such imbalances express themselves in deficiencies in patient care—particularly in lifestyle-related chronic conditions.

Reflections from HEALM’s Katz

In an article reported elsewhere,³ I engaged ACLM leader Katz on their strategic approach with HEALM. He confirms that the HEALM work is transparently political as a step to remove the RCTs barrier to the advancement of the lifestyle medicine clinical model. The target audience is a key stakeholder: nutritional epidemiologists for which they presented an advisory team of impeccable endorsers. They consciously chose to draw narrow boundaries for their engagement. They chose not to stray into the integrative and WSR dialogue, despite the rich resonances. While in the interview Katz did not hesitate to join a growing league of others¹¹ decrying what he calls the “tyranny of the RCT,” any such hair-pulling is not found in the paper. ACLM’s interest as Katz shares was not in pointing out differences, or calling out shortcomings,

but in advancing the field to which ACLM is dedicated: “If you want to wage war, you take up the sword, If you want to make peace you genuflect a little bit. We didn’t wish to look for any non-existent provocation.” Yet in response to a question as to how radical the proposal is, the pressures at the seams of this subservience stretch the threads.

The most popular method for measuring strength of evidence is GRADE¹³ and it depends almost entirely on RCTs. In reality, there is a tyranny of the RCT—the idea that if we don’t know something via the RCT we don’t know it. But in lifestyle medicine, we are interested in lifelong effects that RCTs can’t measure, and in interventions where the placebo may be unethical. Given the growing tyranny of the RCT, [HEALM] is pretty revolutionary ...

We were looking to be narrow as possible in the way we framed this for this to have maximum value. We wanted it to be as conventional as possible. We want it to capture the attention of nutritional epidemiologists. The more radical the proposal, the more conventional the case you want to make. We wanted our citations to be from researchers and journals the people we wanted to influence knew. We stuck close to our narrow proposal to do the systematic review then develop and propose the HEALM model. [Our work with HEALM] is a classic case of if you can’t beat them, join them—then beat them by joining them ...

[With HEALM we are] looking to broaden people’s minds. There is a widespread debate in the peer-reviewed literature and the research community more generally about the nature of evidence for nutrition and other lifestyle interventions. An answer is never better than the question that is asked. There is not only a tyranny of the RCT, there is a tyranny of evidence-based medicine. Evidence-based medicine (EBM) ignores the fact that whoever has the money has the evidence. Pharma has the money. It is true that the evidence of absence is not the absence of evidence. (Interview with David Katz, excerpt from a published interview.)³

These selected representatives of the WSR and integrative health community herald HEALM’s value and express interest in its potential contributions, while, in the main, urging a less compliant line on the RCTs overbearing if not tyrannical position. The ACLM strategically chose to keep the integrative barbarians outside of the gates. Better, for them they judged, tactically, to stay focused on what they portrayed as more narrow lifestyle medicine issues. As politics, this was a move to gain a new respectful place for research on lifestyle medicine on the research throne. It is an internal play for power inside of the court of the RCT king.

Tyranny, down through history, is typically associated with bloodshed. Katz, in the interview, points to the gross financial inequities that tilt even the RCT playing field toward pharma—aside from any recommendation of other research methods as HEALM urges. Rioux associates the imbalance with a sociopolitical structure known to produce population-level murderous outcomes: colonialism. It is beyond this column to examine whether the mayhem in the mainstream biomedical industry—put at just more than 250,000 deaths each year by Hopkins researchers¹⁴—can be causally associated with that industry’s symbiotic relationship with the purportedly tyrannical RCT. (The questions are interesting. What for instance is the count if one considers the deaths and morbidity associated with millions of people who are directed toward pharma interventions rather than the best sort of multimodal, lifestyle medical interventions?)

I join the WSR researchers who offer perspectives here in wishing for the best for the HEALM initiative while simultaneously wondering whether the present power imbalance can be tipped via such tiptoeing around the advocates and defenders of the primacy of the RCT, regardless of its misfit with lifestyle medicine and other whole systems approaches. Perhaps research should be commenced that provides an evidentiary case that will foment pitched rhetorical battle to put an end to the morbidity and mortality that come from the RCTs role in delaying optimal care, and the failure to properly diagnose and treat. Might such research support a movement of resources toward more equitable and diverse models? In the era of chronic diseases and lifestyle-related ill health, is the continued supplication to the RCT a major public health problem?

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