Commentary

Making Evidence from Research More Relevant, Useful, and Actionable in Policy, Program Planning, and Practice

Slips "Twixt Cup and Lip"

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Introduction

The apparent loss of evidence between production and implementation has become a concern of legislators, research funding agencies, academic institutions, and professional associations alike. Researchers and journal reviewers exacerbate this slippage by emphasizing internal validity, often at the expense of the contextual factors that make science relevant to practice. As illustrated by the papers in this supplement to the *American Journal of Preventive Medicine*,[1–15] the contribution to this imbalance from researchers can be offset by their active engagement of the intended users and beneficiaries of the research in applying principles of community-based participatory research (CBPR). From proposed criteria and processes for assessing and reporting external validity, editors of 13 journals considered the tradeoffs in reporting external validity and made recommendations for action for scientific review and publishing of research summarized here. Giving greater attention to external as well as internal validity, to practice-relevance as well as causal certainty, and to community context as well as rigor in data collection, all have potential to ensure that research improves science, policy, practice, and health outcomes.

No one denies the many slips between the cup of science and the lip of application. Clinical practice, public health programs, and health policy all lag in the application of much evidence-based knowledge.[16] The blame falls variously on legislators for their lack of political will, practitioners for their resistance to changing familiar practices, and researchers for their overconfidence that their findings, once published, will speed into practice.[17] The gap between science and practice—what the IOM in the U.S. termed a *quality chasm*—appears to be narrowing only slowly and at best unevenly.[18] Implicated barriers to evidence-based practice are numerous—including misaligned incentives, dysfunctional healthcare organizations, and outdated information systems. The one most cited by practitioners themselves is the lack of relevance or fit of much research to practice; these aspects of external validity are too seldom reported with published research.[19] One implication of this gap is that if we want more evidence-based practice, we need more practice-based evidence.[20]

This supplement to the *American Journal of Preventive Medicine* presents a range of alternatives suggesting and documenting in various ways that the development and application of research products will be improved by greater engagement in the research of those who would use or benefit from the research. This range of alternatives falls under the broad rubrics of participatory research and action research, and the more particular community-based participatory research.

The "supply-driven" pipeline for getting evidence into practice has had it successes but risks losing sight of the "demand" side of the problem. Delivering a highly purified review or guideline that emphasizes carefully controlled trials with high internal validity runs the risk of ignoring those elements that make applied research useful, appealing, and relevant to those who would apply it. Unless the research clearly addresses questions important to practitioners and produces findings that can be readily applied to their populations in their settings, they remain unlikely to consume it.[21] Unfortunately, practitioners (including policymakers and program planners) often do not find the research evidence relevant to either their needs[22] or those of their patients or populations.[23] Practitioners and decision makers in clinical, community, and policymaking roles seek evidence from typical conditions. Rigid protocols designed to ensure the internal validity of intervention research (for example, highly selected patient populations, in or under the experimental control of world-class academic institutions) often make findings seem irrelevant for most of the intended users.

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0749-3797/09/$–see front matter
doi:10.1016/j.amepre.2009.08.017

Restricting the Pipeline's Flow

The transmission of science into practice will always[24] remain erratic as long as it emphasizes the peer review of grant proposals, manuscripts, and promotion decisions, which restricts the flow of potentially practice-relevant evidence. By imposing experimental criteria too rigidly or exclusively in the successive stages of judging the science and the scientists, the process gives priority weight to causal certainty, that is, confidence that the outcomes can be attributed to the intervention, without commensurate attention to relevance, cost, or certainty that the intervention could be used and will work in patients or populations outside the research setting.[25]

The participatory, practice-based conceptualization of research would bring the practitioners and researchers closer together in the planning, conduct, and interpretation of research, ideally under real-time circumstances of practice, in the form of action research, participatory research, practice-based research networks (PBRNs),[26,27] continuous quality improvement (CQI) programs,[28] and practical trials.[16,29] The promise inherent in these approaches is that the involvement of practitioners in adapting the research findings or reframing the research itself in local contexts ensures greater relevance and fit with the practice circumstances.[27] Extending efficacy studies to "effectiveness" or "practical" trials[16] has caught the interest of large health plans and insurers (www.cmtpnet.org) who want more useful answers to important issues affecting their populations. These trials emphasize broadly inclusive populations, interventions implemented under more typical conditions, comparisons to existing care or other treatments (rather than to no treatment or placebo), and clinically important outcomes. The projects reported in this supplement illustrate some of these elements of research carried out by a new generation of Robert Wood Johnson Foundation (RWJF) Clinical Scholars, their community partners, and their academic mentors. Such approaches have much to contribute to the emerging field of comparative effectiveness research.

Some Journal Editors Examine the Publication Problem

Although these efforts are growing, they remain obscured by the prevailing models of academic research published in most health science journals. To examine approaches to improving the relevance, utility, and external validity of published research—with the support of the RWJF, the Agency for Healthcare Research and Quality, the NIH Office of Behavioral and Social Sciences Research, and in-kind support from the CDC—a meeting was convened of 13 journal editors to discuss how to improve attention to external validity (or applicability) of the research they publish. Publication of research, whether as individual studies or systematic reviews, influences how research is designed, how easily it can be used, and how researchers are rewarded professionally. With participation from federal agencies, a philanthropic foundation, and members of two prominent task forces responsible for synthesizing evidence on clinical and community interventions, these editors had all expressed interest in the issues of external validity. The meeting was hosted and co-chaired with the first two authors by Dr. Alice Ammerman, Director of the Center of Excellence for Training and Research Translation at the University of North Carolina at Chapel Hill (for details of the meeting and materials see www.re-aim.org/2003/whatsnew.htm and go to "External Validity Meeting. . ."; see also an earlier commentary by the Editor and Associate Editors of this journal in response to the meeting).[30]

Campbell and Stanley's classic definition of external validity was used: inferring "to what populations, settings, treatment variables, and measurement variables can [the effect] be generalized?"[31] Given evidence that external validity issues are reported far less frequently than other methodologic issues,[32] participants agreed that journals should improve reporting of external validity in research studies. Incomplete information to judge external validity creates several problems. Practitioners and policymakers are left to guess whether a study applies to their local setting or population or whether the intervention could be implemented given their staffing and resources. At the same time, systematic reviews cannot examine whether factors that may affect external validity (for example, the level of training and involvement of staff, organizational characteristics, inclusion and exclusion criteria) function as important effect modifiers. Similarly, they cannot always determine when it is appropriate to pool particular studies in meta-analyses.

Meeting participants identified categories of information relevant to external validity and agreed on the importance and feasibility of reporting the following:

1. recruitment and selection procedures, including participation rate and representativeness for individual subjects, intervention staff, and delivery settings;
2. level and consistency of implementation across program components, settings, staff, and time; includes degree to which intervention is modified;
3. attrition and long-term effects of the intervention on research subjects, intervention staff, and sites; includes loss-to-follow up for long-term outcomes and degree to which intervention is revised, discontinued or institutionalized;
4. impact on outcomes important to patients, practitioners, and decision makers; includes disease-specific outcomes, quality of life, program cost, and adverse consequences.

Editors' Considerations and Caveats

Participants did not agree uniformly on the remedies to address this imbalance. Proposed solutions entail various barriers, limitations, and tradeoffs. Editors acknowledged the tensions in efforts to conduct and report more relevant research:

1. External validity must be considered in the context of specific questions. One cannot assess the external validity of a particular study without reference to a specific clinical or policy question of interest. Determining whether a study is broadly applicable across many settings and populations (of interest to guideline developers, for example) is different than judging whether a study from one setting can be applied to a specific setting of interest to local decision makers. Both issues, however, require authors to report similar information.
2. Journals serve different roles as builders of science and as shapers of policy and practice. Journal editors and many of their constituents usually consider the primary role of journals to be building science rather than accelerating translation of those findings into practice. Current journal rankings based on impact-factor scores emphasize citations by other scientific publications rather than influence on practice or policy. A complementary ranking of journals by a policy-and-practice-impact scoring system might be helpful in giving credit for the practical value of some publications.
3. It may be more useful to emphasize principles of reporting external validity than specific rating approaches. There is general agreement on broad principles for reporting external validity.[33] Applying these principles reliably in the review process, however, might require more specific rating criteria. Agreement on precise criteria might be more difficult, as criteria may be specific to the topic and context—for example, critical intervention details will differ for studies of community interventions from those of drugs and devices.
4. External validity should be addressed in all systematic reviews. Considering external validity is especially useful in systematic reviews, which form the basis for practice guidelines and policy recommendations. Assessing whether results are consistent across settings may provide insights on external validity that cannot be gleaned when examining single studies.
5. Costs must be considered part of validity measures. Expense is not usually thought of as part of validity but is of particular concern to program planners and policymakers. Relevant cost concerns such as start-up costs versus on-going costs, and expenditures versus opportunity costs can be challenging to report. Nonetheless, editors felt it should be possible for most studies to report a set of minimal, standard cost-of-implementation, reach, and value-of-outcomes metrics.[34]
6. There are tradeoffs between maintaining the "fidelity" or "integrity" of an intervention versus adapting it to local conditions. Users of research will inevitably need to weigh the relative merits of adhering strictly to an intervention as originally designed and tested, versus adapting it to their population, circumstances, and local needs. Better reporting of how design of studies affects applicability of the intervention to the patient population will allow end users to judge the tradeoffs in adapting how they enroll participants or deliver the intervention. Reporting on context and organizational capacity could enhance such communication.
7. Tension and tradeoffs exist between internal and external validity. Improving attention to external validity need not be at the expense of internal validity, and they should not be pitted against each other. More consideration of external validity in funding, reporting, synthesis, and application of research can help create a better balance of research that is both credible and relevant to policy, programs, and practices.

Recommended Actions for Journals

The editors produced a series of recommendations for actions they and some of their journals could take to move this agenda forward:

1. Publish editorials on external validity, possibly coordinated across journals.
2. Feature some exemplary studies or a special issue with presentation of factors affecting external validity.
3. Use tools for rating external validity and pilot test external validity reporting principles or rating criteria, such as those suggested by the U.S. Preventive Services Task Force and the Community Preventive Service Task Force.
4. Encourage journal reviewers to comment explicitly on the external validity of manuscripts.
5. Expand online publication of protocols or details relevant to external validity that cannot fit into published manuscripts.
6. Engage a wider range of journals and other organizations in these efforts.
7. Index keywords relevant to key dimensions of external validity.

Summary and Conclusion

Journal publication is only one of many obstacles to increased and fuller flow of research into practice, from the process by which research is conceived, reviewed and funded, to how researchers are trained and promoted, to how studies are synthesized for guidelines and other policy decisions. Some of these factors have

Table 1. Summary of the main points of this commentary

Summary

- One reason for the slow and incomplete transfer of research findings to practice is limited reporting of information on external validity and relevance to particular situations.
- Participatory and practice-based research conducted by clinical scholars, their community partners, and their mentors illustrate in this supplement to the *American Journal of Preventive Medicine* many of the external validity advantages of these approaches to research.
- Editors of 13 journals attended a meeting on this issue and agreed on ways that journals could improve reporting on external validity in publications.
- The editors concluded that focusing authors' and reviewers' attention on principles for reporting external validity is more feasible and helpful than using specific review criteria.
- Recommended actions included publishing editorials and exemplary articles on external validity, indexing key words related to external validity, and expanding use of online supplements and resources.

been examined recently, specifically in relation to HIV-AIDS studies.[35] The RWJF Clinical Scholars and their colleagues have demonstrated in their papers in this supplement to the *American Journal of Preventive Medicine* several of the ways more participatory and practice-based research can contribute to closing some of these gaps. A meeting of journal editors and other organizations came to consensus on the need to address issues of external validity more systematically and on a series of practical measures to improve the applicability of the research they publish. Similar attention needs to be paid to other opportunities between the conception of research questions and the dissemination of research products to increase their relevance to practice (Table 1).

The authors acknowledge that there are no conflicts of interest, including commercial interests, relationships, or affiliations relevant to the subject of this manuscript. The views expressed are those of the authors and do not reflect official policy of the Agency for Healthcare Research and Quality or the USDHHS, or of the other agencies or organizations that sponsored the meeting of journal editors: the Office of Behavioral and Social Sciences Research of NIH, the RWJF, and the CDC. All authors contributed to the drafting and review of the content of the article. LWG is the guarantor.

No financial disclosures were reported by the authors of this paper.

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Appendix A: Sources for More Information

Detailed report on the meeting of journal editors:
www.re-aim.org/2003/publications1.html
(select Meeting Summary and Recommendations . . .)
Factors that can affect external validity:
www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1488890
(Rothwell PM. PLoS Clin Trials 2006, 1(1):e9)
Intervention reporting template addressing external validity:
www.center-trt.org/index.cfm?fa=evidence.intervention
For discussion of external validity:
www.socialresearchmethods.net/kb/external.php

Appendix B. Provenance of the Article

The meeting of editors from which this article draws its recommendations was supported by the Agency for Healthcare Research and Quality, the Office of Behavioral and Social Sciences Research of the NIH, and the CDC, all of the USDHHS, and the RWJF. Besides the editors or associate editors of 13 journals, the meeting was attended by representatives of the two major U.S. systematic review and guideline development bodies (the U.S. Preventive Services Task Force and the Task Force on Community Preventive Services), and by Professor Penny Hawe of the University of Calgary in Canada, codirector of the International Collaborative on Complex Interventions supported by the Canadian Institute for Health Research.

The authors organized (Green and Glasgow), sponsored (Atkins), and attended (all four authors) the meeting of editors from which the main thrust of this article is derived. Green and Glasgow co-authored a pair of previous publications on the neglected problem of external validity and outlined a series of guidelines for reporting external validity. Green has written extensively on program planning, dissemination, and bridging science and practice, and has served as director of three federal offices in the USDHHS between his academic appointments at UC Berkeley, Johns Hopkins, Harvard, University of Texas, University of British Columbia, and UCSF. Glasgow has published widely on measures to assess the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM model) of interventions. Atkins is director of the QUERI Program and Associate Director for Health Services Research & Development for the Department of Veteran Affairs Health Services; Stange is the editor of the *Annals of Family Medicine* and a professor of Epidemiology & Biostatistics, Oncology, and Sociology at Case Western Reserve University. He has chaired the National Advisory Committee of the Prescription for Health Practice-Based Research Grant Program of the RWJF, of which Green and Glasgow were members.