Implementation research design: Integrating participatory action research into randomized controlled trials

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Abstract

Background:

A gap continues to exist between what is known to be effective and what is actually delivered in the usual course of medical care. The goal of implementation research is to reduce this gap. However, a tension exists between the need to obtain generalizeable knowledge through implementation trials, and the inherent differences between healthcare organizations that make standard interventional approaches less likely to succeed. The purpose of this paper to explore the integration of participatory action research and randomized-controlled trial study designs to suggest a new approach for studying interventions in health care settings.

Discussion:

We summarize key elements of participatory action research, with particular attention to its collaborative, reflective approach. Elements of participatory action research and randomized controlled trial study designs and discussed and contrasted, with a complex adaptive systems approach used to frame their integration.

Summary:

The integration of participatory action research and randomized controlled trial design results in a new approach that reflects not only the complex nature of healthcare organizations, but also the need to obtain generalizeable knowledge

regarding the implementation process.

Background:

A gap exists between what is known to be effective and what is actually delivered in the course of usual medical care in this country[1-5]. The aim of implementation research is to reduce this gap through identifying methods to improve clinical practice in a generalizeable way. Implementation research tries to understand how an intervention designed to improve clinical practice and tested in a limited, controlled setting can be implemented across a wide range of settings. These implementation research efforts have ranged from interventions focusing on individual provider behavior, to those with a more general educational focus, to those designed to address specific barriers to change, but these efforts share in common only small to modest effects on outcomes [6-10].

Interventions that are multi-pronged in approach, or which target organizations rather than individuals, may be more likely to be successful [11-13]. However, these may also be more difficult to translate from one institution or setting to another because of inherent differences between institutions. These differences arise because healthcare organizations are not static, but are constantly adapting and evolving in response to changes in their local environments, making one-size-fits-all interventions that attempt to reduce local variation less likely to be successful.

This leads to a profound dilemma in implementation research: how do we design interventional trials that are generalize-able, but also have enough flexibility to be meaningful and more likely to be successful locally? To put this another way,

how can we marry what many consider to be the ideal of the randomized-controlled trial (RCT) with the difficulty of retaining interventional fidelity across institutions, and with the more individualized, institutional needs of institutions when it comes to actually making an intervention work on a local level? The goal of this paper it to explore the integration of participatory action research (PAR) with a randomized-controlled trial (RCT) study design as a mechanism for informing and improving our ability to translate research findings into general practice.

Why there is a need to consider different research methods in healthcare organizations:

A growing literature suggests that health care organizations are complex adaptive systems (CAS's) [13-17]. Complex adaptive systems are comprised of individuals who learn, inter-relate, and self-organize to complete tasks. They also co-evolve with their environment, responding to external forces in ways that in turn re-shape their external environment. Most importantly, complex adaptive systems are characterized by non-linear interactions that may lead to outputs, or "emergent properties," that are not entirely predictable.

Conceptualizing health care organizations as complex adaptive systems has important implications for how we think about intervening in such systems, as the CAS framework reinforces the idea that each system is unique, and that interventions cannot easily be moved from one organization to the next with

predictable results [13, 17, 20, 21]. The CAS framework goes further, however, by suggesting that it is only through leveraging each system's pattern of interconnections between individuals that interventions will be optimally effective. Thus, to have the biggest impact, it is necessary to not only take into account differences between systems, but to exploit these in a way that will lead to maximal results. The implication is that the local participants will have the greatest ability to accomplish this.

The idea of performing a randomized controlled trial (RCT) in complex adaptive systems requires us to re-think several key points about RCT's. First, the notion that a single intervention can be applied in a standardized way is not applicable. Therefore, we need to pay attention to what elements of an intervention could or should be common to all sites, and what can be locally varied. Second, the CAS framework should lead us to rethink the idea of monitoring fixed "endpoints" at certain pre-specified points in time. Instead, we must pay attention to the implementation of an intervention throughout time, to how the intervention impacts the interdependencies within the system, and to the potentially unpredictable impacts of interventions. This requires a different level of monitoring, one that can best be done by local participants. Finally, the application of CAS to clinical systems encourages the idea that the intervention itself will evolve over time, as the organization in which it is implemented changes. This may make the intervention more or less effective over time.

Thus, reconceptualizing clinical and healthcare organizations as CAS makes new approaches to implementation research necessary. A way of not only

accounting for but taking advantage of local differences in health care systems is needed, but needs to be balanced by a research design framework that allows for some level of generalizability. Because of its consistency with CAS principles, PAR may be an appropriate approach to consider for implementation studies in health care settings.

Participatory action research defined:

Participatory action research is a technique derived over the last 40 years from the sociological, organizational, educational, and evaluation research literatures[22-24]. It is a design that partners the researcher and participants in a collaborative effort to address issues in specific systems. It is a collaborative, cyclical, reflective inquiry design that focuses on problem solving, improving work practices, and on understanding the effect of the research or intervention as part of the research process. It explicitly calls for making sense of the impact of change, and refining actions based on this impact. Essential elements and typical methods of action research are shown in Table 1, derived from reviewing definitions of PAR across disciplines and qualitatively analyzing these definitions for themes and commonalities.

Two systematic reviews of what might be considered PAR in health care settings are available. The UK National Health Service funded a systematic review of action research, published in 2001. "Initiatives that persisted at the same location were found in 32 studies (54%) and, in a small number (four studies,

13%), an effect beyond their location was claimed." In 2004, the Agency for Healthcare Research and Quality sponsored an evidence report on community-based participatory research. This review found only 12 completed interventional studies, 4 of which were RCT's. Findings revealed modest positive health outcome findings, but the reviewers could not determine whether this benefit could be attributed to the community-based participatory research methods. Both reviews suggest the need to further understand what constitutes high quality PAR and how best to evaluate the quality and outcomes of such research.

Similarities and differences between participatory action research and quality improvement strategies:

While the name "participatory action research" is not widely used in clinical circles, many continuous quality improvement (CQI) techniques, such as Deming's total quality improvement, Six Sigma techniques, and the Institute for Healthcare Improvement's learning collaboratives, have features that are consistent with PAR. First, they call for involvement of a team of key individuals, particularly those with a fundamental knowledge of the context and need for improvement, to be involved in the process. Second, they call for focusing a team around a specific problem. Third, they involve a cyclical approach with repeated cycles of incremental improvement, analogous to "plan-do-study-act." Finally, both PAR and CQI are meant to be transformative for the individuals involved, so that they have the skills to problem solve in new scenarios.

An important difference between PAR and CQI is that the latter typically assumes a reductionist system that can be improved by looking at specific steps in healthcare processes. PAR's emphasis on the relationships between individuals in the system, and their ability to self-organize over time, implies an inherent applicability to CAS. An additional difference between PAR and CQI approaches is that the primary goal of the latter is to do an intervention, while that of the former is also to learn something about the implementation process itself.

How participatory action research may be integrated with randomized controlled trails in implementation research design

We propose integrating the RCT and PAR approaches to retain the "rigor" of the RCT with the local sensibility brought by PAR. This integration informs several elements of a combined design: the intervention, the endpoints, and the process of measurement. Table 2 summarizes key elements of PAR and RCT, and how these specific elements may be incorporated into an integrated PAR/RCT approach.

To integrate PAR into an RCT framework, we will need to move away from the proscribed interventions of the "traditional" RCT in favor of locally designed interventions that meet a general goal or strategy. Elements of PAR may be important additions to intervention design in implementation research, particularly the need for local input into intervention design, and the need for sites to continue to change over the course of an intervention based on the success of

the intervention. PAR may help us to focus less on the medical content of the intervention and more on the processes of group facilitation, reflection, and relationship building that may be the more generalizeable components of the intervention. These activities should be made explicit elements of intervention design.

Non-healthcare literatures suggest that participation and decisional control are facilitators of organizational learning and change, overcoming barriers such as established routines and political barriers. Participation may also facilitate learning, in turn leading to increased likelihood of longer-term changes in behavior. These attributes may also facilitate the successfully implementation of interventions to improve health care delivery.

There may also be benefit to integrating the ability to modify the intervention plan into the research design, by building reflection into the intervention. Interventions that allow participants to respond to incremental changes in the outcome variables during the course of the intervention period may allow for adaptation of the intervention in ways that may make the intervention more effective. These adaptations and their impact are important to understand. Rather than undermining the ability to generalize from results, they may actually lead to findings that improve the ability of subsequent settings to implement the intervention. An example of such a strategy may include result feedback during specific ranges of time, such as sharing the impact of an intervention on process or patient outcomes.

To integrate PAR and RCT, new approaches to defining endpoints and their measurement will be required. In addition to the clinical endpoints that relate to the disease or population in question, endpoints chosen by local participants to help them monitor their progress should be added. Instead of pre-defined time periods at which endpoints are measured, the process of reflecting on the impact of an intervention in the clinical setting should become continuous, and the time it takes to implement an intervention may become an endpoint. This will allow for feedback that will help to strengthen the intervention, and will lead to a greater understanding of how the implementation process unfolds in each clinical setting. This understanding will be key to our ability to implement interventions successfully in other clinical settings. Thus, a greater appreciation of the process of intervention is a key lesson that must be derived from intervention studies.

Summary – why including participatory action research may improve our ability to design more effective interventions and improve patient outcomes

At first glance, the suggestion to integrate RCT and PAR approaches may seem contradictory – the former attempts to implement standardized interventions in an effort to reduce bias and increase generalizeability, while the latter is concerned with an individual system and its unique needs, rejecting the idea of the "external researcher." However, implementation research always occurs in the context of an organization, and for our efforts to become successful, new methodologies

and approaches that recognize and respect each organization's unique characteristics but still allow for a more universal understanding to be gained must be developed. Rather than using standardized approaches to reduce bias, being explicit about differences and their impacts that will allow us to better understand the process of implementation, and it is this understanding that will lead to more successful implementation strategies. We suggest that an approach that builds on and integrates the RCT and PAR characteristics are more likely to advance our efforts than either approach alone.

The addition of elements of PAR to interventional research studies may be a way to better meet the needs of implementation research: to meet the needs of generalizeability while respecting local conditions that are important in individual health care settings. Additionally, these elements are well-suited to specific aspects of health care systems that reflect their complexity: the role of relationships among healthcare workers, managers and patients in potentially unpredictable settings. Incorporating PAR principles may provide us with a deeper understanding of health care systems and what is needed to improve them. The results of implementation studies utilizing a practice facilitation approach suggests support for this approach, as practice facilitation focuses on improving relationships and communication within health care organizations.

Additionally, the explicit inclusion of reflection and "sensemaking" is an important component of the PAR methodology that is critical for understanding CAS, where unanticipated or unexpected results of interventions may occur. The process of looking critically at the impact of an intervention and adapting to this impact may

lead to more effective interventions. The application of sensemaking to organizations outside of health care supports this idea.

The approach of adapting elements of PAR to RCTs may seem problematic to both the strict adherents of both PAR, and to those of RCTs. For the former, the attempt to fit an approach that is meant to focus exclusively on the needs of participants into an intervention that is on some level superimposed may seem to negate the very principles of PAR. For the latter, the incorporation of this degree of latitude into an intervention may seem to nullify the purpose of performing an RCT, and the ability to generalize from its results.

We believe that these criticisms miss an essential point of this approach – that organizations are dynamic, and that a greater understanding of the diverse processes through which general strategies may be implemented successfully is critical to implementation research. The question is not whether a diabetes registry or a clinical reminder applied in a specific way can lead to predictably improved outcomes for diabetic patients in six months; the question is whether these approaches applied uniquely in the contexts of individual health care systems is more likely to change these systems in sustained ways that will lead to improved outcomes. A key issue is whether an intervention is more or less likely to help to change the interconnections between elements of the system in a way that will lead to improved care. We can gain an understanding of whether certain types of interventions can be utilized in a manner across individual clinical systems such that outcomes are likely to improve. Instead of focusing on whether interventions are faithfully applied, we can learn from the myriad ways

that participants apply interventions in their own settings, and from the degrees of change in outcomes that result.

Incorporating PAR principles may make the task of interpreting results of implementation trials more challenging, as it may be more difficult to assess true improvement in the setting of evolving interventions in organizations over time. However, they may also make interventions better suited to long-term successes by enabling us to implement more lasting organizational changes through the adaptive participation of those individuals who are most involved in the local process of care.

List of abbreviations:

PAR – participatory action research

RCT – randomized-controlled trial

CAS – complex adaptive system

Competing interests:

The authors declare that they have no competing interests.

Authors contributions:

JAP conceived the manuscript, conducted the initial review of studies of participatory action research, and completed the first draft of the manuscript.

LL performed additional literature review, contributed to the first draft of the manuscript, and completed significant revision as part of the peer-review process.

HL performed additional literature review, contributed to the application of the CAS framework, and contributed to the revision of the manuscript.

JH contributed to the conceptualization and first draft of the manuscript.

RRM contributed to the initial development of the manuscript, the application of the CAS framework, and the revision of the manuscript.

All authors read and approved the final manuscript.

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References:

1. Committee on Quality of Health Care in America, Institute of Medicine. Crossing the quality chasm: a new health care system for the 21st century. Institute of Medicine, National Academy Press. Washington, DC, 2001. Available from: URL: http://www.nap.edu/books/0309072808/html/.

2. Wachter RM. The end of the beginning: patient safety five years after 'To Err is Human'. Health Affairs-Web Exclusive. 2004;W4:534-545.

3. Lenfant C. Clinical research to clinical practice—Lost in translation? N Engl J Med, 2003; 349: 868-874.

4. Asch SM, Kerr EA, Keesey J, Adams JL, Setodji CM, Malik S, McGlynn EA. Who is at greatest risk for receiving poor-quality health care? N Engl J Med 2006;354:1147-56.

5. Oxman AD. No magic bullet: a systematic review of 102 trials of interventions to improve professional practice. Canadian Medical Assoc J 1995;153:1423-31.

6. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, Whitty P, Eccles MP, Matowe L, Shirran L, Wensing M, Dijkstra R, Donaldson C. Effectiveness and efficiency of guideline dissemination and

implementation strategies. Health Technol Assess. 2004 Feb;8(6):iii-iv, 1-72. Review.

7. Oxman AD. No magic bullet: a systematic review of 102 trials of interventions to improve professional practice. Canadian Medical Assoc J 1995;153:1423-31.

8. Bero LA, Grilli R, Grimshaw JM, Harvey E, Oxman AD, Thomson MA. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care Review Group. BMJ 1998;317:465-8.

9. Solberg LI, Kottke TE, Brekke ML, Magnan S, Davidson G, Calomeni CA, Conn SA. Failure of a continuous quality improvement intervention to increase the delivery of preventive services. A randomized trial. Eff Clin Pract 2000;3(3):105-15.

10. Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, Rubin HR. Why don't physicians follow clinical practice guidelines? A framework for improvement. Jama 1999;282(15):1458-65.

11. Weingarten SR, Henning JM, Badamgarov E, Knight K, Hasselbad V, Gano A, Ofman JJ. Interventions used in disease management programmes for patients with chronic illness – which ones work? Meta-analysis of published reports. BMJ 2002; 325.

12. Katon W, Russo J, Von Korff M, Lin E, Simon G, Bush T, Ludman E, Walker E. Long-term effects of a collaborative care intervention in persistently depressed primary care patients. J Gen Intern Med 2002;17(10):741-8.

13. Stroebel CK. McDaniel RR Jr. Crabtree BF. Miller WL. Nutting PA. Stange KC. How complexity science can inform a reflective process for improvement in primary care practices. [Journal Article. Research Support, N.I.H., Extramural. Research Support, U.S. Gov't, P.H.S.] *Joint Commission Journal on Quality & Patient Safety. 31(8):438-46, 2005 Aug.*

14. McDaniel RR Jr, Driebe DJ. Complexity Science and Health Care Management. Advances in Health Care Management. 2001;2:11-36.

15. Plsek PE, Greenhalgh T. Complexity science: The challenge of complexity in health care. Bmj 2001;323(7313):625-8.

16. Miller WL, McDaniel RR, Jr., Crabtree BF, Stange KC. Practice jazz: understanding variation in family practices using complexity science. J Fam Pract 2001;50(10):872-8.

17. Plsek P. Redesigning Health Care with Insights from the Science of Complex Adaptive Systems. In: Crossing the Quality Chasm: A New Heath System for the 21st Century: National Academy of Sciences; 2000. p. 309 - 322.

18. Cilliers, P. Complexity and Postmodernism: Understanding Complex Systems. New York, NY: Routledge 1998.

19. Maguire S, McKelvey B, Mirabeau L, Oztas N. Complexity Science and Organization Studies. In: The SAGE Handbook of Organization Studies, SAGE Publications; 2006. 2nd ed, 165-214.

20. Litaker D, Tomolo A, Liberatore V, Stange K, Aron D. Using Complexity Theory to Build Interventions that Improve Health Care Delivery in Primary Care. J Gen Intern Med 2006; 21:S30-4.

21. Leykum LK, Pugh J, Lawrence V, Parchman M, Noel P, Cornell J, et al. Organizational interventions employing principles of complexity science have improved outcomes for patients with type II diabetes. Imp Sci 2007; Aug 29:2:28.

22. Whyte. WF Participatory Action Research, Sage, Thousand Oaks, CA. 1991.

23. Waterman H, Tillen D, Dickson R, de Koning K. Action research: a systematic review and guidance for acceptance. Health Technology Assessment, 2001; (5(23): 1-174

24. Viswanathan M. Ammerman A. Eng E. Garlehner G. Lohr KN, et al. Community-based participatory research: assessing the evidence. Evidence Report/Technology Assessment No. 99. AHRQ Publication 04-E022-2. Rockville, MD: AHRQ. July 2004.

25. Bloom HS, Ed. Learning More from Social Experiments: Evolving Analytic Approaches. Russel Sage Foundation, New York, New York, 2000

26. Aaron KF, Stryer D. Editorial: Moving from rhetoric to evidence-based action in health care. JGIM, 2003;18:589-91.

27. Hawkins P. A centennial tribute to Gregory Bateson 1904-1980 and his influence on the fields of organizational development and action research. Action Research 2004, 2:1-13.

28. Peters M, Robinson V. The origins and status of action research. The Journal of Applied Behavioral Science. 1984;20(2):113-124.

29. Marsick VJ, Gephart MA. Action research: Building the capacity for learning and change. Human Resource Planning, 2003;26:14-18.

30. Macaulay AC, Commanda LE, Freeman WL, Gibson N, McCabe ML, Robbins CM, Twohig PL. Participatory research maximizes community and lay involvement. BMJ 1999;319;774-778.

31. Elden M, Chisholm RF. Emerging varieties of action research: Introduction to the special issue. Human Relations, 1993;46:121-142.

32. Heron J. Co-Operative Inquiry: Research Into the Human Condition. Sage Publications, Thousand Oaks, CA, 1996.

33. Bray JN, Lee J, Smith LL, Yorks L. Collaborative Inquiry in Practice: Action, Reflection, and Making Meaning. SAGE Publications; Thousand Oaks, California, 2000.

34. Kemmis, S. and R. McTaggart. The Action Research Planner, 3rd ed, Geelong: Deakin University, 1988.

35. Deming WE. Out of crisis. Cambridge (MA): MIT Press; 1982.

36. Chassin MR. Is health care ready for Six Sigma quality? Milbank Q 1998:76(4):565-91, 510.

37. Pexton C. Measuring six sigma results in the health care industry. http://healthcare.isixsigma.com/library/content/c040623a.asp (accessed 9/4/06).

38. Hall JE. Professionalizing action research—a meaningful strategy for modernizing services? Journal of Nursing Management, 2006; 14:195-200.

39. Torbert. W. The distinctive questions developmental action inquiry asks. Management Learning. 1999;30:189-206.

40. Cooperider, D. L. & Srivastva, S. "Appreciative Inquiry in Organizational Life." Research in Organizational Change and Development. 1987;1:129-169.

41. Reason P. Choice and quality in action research practice. Journal of Management Inquiry, 2006;15:187-203.

42. Viswanathan M, Ammerman AS, Lohr KM, Lux L, Sutton SM, et al. CBPR Reviewer Checklist. July 2004. Available from URL: http://www.rti.org/pubs/CBPR_rev_check.pdf

43. Greenwood DJ, Levin M. Introduction to Action Research. Sage Publications. Thousand Oaks, California, 1998.

44. Cooperrider DI, Srivastva S. Appreciative inquiry in organizational life. Research in Organizational Change and Development. 1987;1:129-169.

Table 1: Essential elements of participatory action research

Quotes from Published Definitions	References
Names Used	
Participatory action research Qualifiers: cooperative inquiry; appreciative inquiry; community-based participatory research; action learning; action science; developmental action inquiry	22-24, 29-34, 38-44
Purpose of the Action Research	
Generation of new knowledge Qualifiers: practice-grounded, compelling enough to motivate to action; answer a question of importance to each other	24,26,28,30,32, 33,44
Change Qualifiers: social change; improvement; improve health / well-being; take action; solution generation; planning action steps; engage in quest for information / ideas to guide future actions	22-24,26,29-31
Educating	23,24,26,30
Theory generation or refinement	23
Relationship building Qualifiers: strengthen relationships among group members, learn to integrate individualizing characteristics with a deeper communion with others and the world; involvement;	23,32
Developmental/Transformative for the individuals or organizations involved Qualifiers: a re-educative process that develops capabilities and transforms individuals / teams through experiential engagement; empowerment; reciprocal transfer of expertise	23,24,29
Methods	
Problem-focused Qualifiers: problem identification; diagnosing a problem; define a pressing problem; an agreed area of human activity; solution generation; planning action steps; engage actively in the quest for information and ideas to guide future actions	22,23,28-33
Systematic	26,30
Cyclical Qualifiers: emergence; adaptive cycles of action-feedback-action-feedback-action; repeated episodes of reflection and action; between meetings, members inquire into their own practice, observe, and implement new actions to help learn something new about the question; four phases of reflection and action; experimentation; learning at each step to inform the next set of decisions / actions; evaluation leads to diagnosing the situation anew based on incremental learnings	23,28,29,31-33
Reflective Qualifiers: self-reflective; members reflect together on their work; inquiring deeply into assumptions and root causes, and	23,32-34

transferring learning at multiple levels	
Collaborative Design and Evaluation Qualifiers: partnership; collective; group activity; mutualistic; inclusive; collaboration shapes and transforms methods; co-learning; participation of all relevant constituencies or stakeholders; involve all participants in all aspects of the research process; organization members participate throughout the research process from the initial design to the final presentation of results and discussion of their implications; reciprocal transfer of expertise; shared decision making power; mutual ownership of the processes and products of the research enterprise; facilitators and group participants co-author reports to present findings; participate in the research processes, which in turn are applied in ways that benefit all participants; multiple person, multiple perspective with participants as co-researchers	22-24,26-33,43
Context specific Qualifiers: Must be applicable to the system in which the inquiry takes place	23,44
Studying the whole or the patterns rather than the parts	27,29
Qualitative and quantitative data collection and analysis Qualifiers: mixed method designs collecting/analyzing both qualitative and quantitative data in single study; concurrent triangulation with multi-strand, multi-wave design; data collected/analyzed simultaneously/iteratively	23,28
Who	
Researchers Qualifiers: Professional action researchers, core research team members, researchers	22-24,32,43
Whoever is affected by the problem being studied Qualifiers: Requisite variety; system members; communities; those affected by the issue being studied; representatives of organizations; members of an organization or community seeking to improve their situation; group of peers	24,26,32,33,43,44
Fields Represented	
Health Related: Public Health, Primary Care, Patient Care, Nursing, Health Education, Health Sociology, Disability Research, Environmental Health, Injury Research, Mental Health, Reproductive Health *Non-Health Related*: Anthropology, Business Administration (Organizational Change/Development, Management, Human-Information System Interfaces), Sociology, Community Development, Community Psychology	

Table 2: Elements of PAR, RCT's, and integrated PAR/RCT

PAR	RCT	Integrated PAR/RCT

Collaborative design	Externally created, standardized interventions	Key elements of intervention are locally implemented based on collaborative discussion
Acknowledgement of unique local environments	Uniqueness minimized through random assignment of sites and interventions	Incorporation of local conditions into overarching approaches
Reveal biases	Reduce bias	Use bias to form basis of generalizeable understanding
Reflective process throughout intervention	Endpoints / measurement set in advance	Time function or endpoints may vary within boundaries Reflection both within and across sites
Local applicability	Generalizeability	Use local findings to inform universal understanding
No comparisons, internal focus	Comparisons between arms	Comparisons based on “content analysis” of internal understandings and lessons
Internal control	External control	Joint control